

DIGITAL PRINTING PRODUCTS REGULATORY GUIDELINES AND STANDARDS



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Product sustainability is an important driver in today's market environment, when combined with safety standards it plays a key role in consumer buying decisions. Clariant recognizes the importance of sustainability for customers and incorporates sustainability as one of five key corporate strategic pillars in its business strategy.

The challenge we all face is that the global scope of regulatory standards, laws, guidelines and labels, combined with brand owner requirements, continues to evolve, becoming more complex and dynamic. Accordingly, it can become difficult to assess the importance and consequences of these guidelines when enabling customers to identify long-term strategic market advantages.

Digital printing continues to grow and expand its presence in an increasing range of commercial and industrial applications, including sensitive markets such as packaging. A key prerequisite in the ink development process is to ensure that the colorants are compliant with the regulatory guidelines and standards in a dynamic market environment.

The aim of this publication is to provide additional support for decision makers when identifying colorant options for use in digital print applications where specific regulatory issues apply in the end-user market.

The range of products described is a selection from Clariant's comprehensive portfolio of organic colorants for digital & analog printing, coating and plastic applications.

Due to the dynamic nature of regulatory guidelines and standards, the content can only provide a snapshot of the status based on information at the date of publication. You are welcome to contact the Clariant team for assistance on any additional regulatory topics.

KEY REGULATORY TOPICS COVERED ARE:

- Swiss Ordinance: Positive list for substances used on/in consumer goods articles
 - Recommendation BFR IX: Purity requirements for colorants used in polymer consumer goods
 - European Resolution AP (89)1: Purity requirements for colorants used in food packaging plastics
 - Regulation (EU) No. 10/2011: Regulation for plastic materials and articles used in food packaging
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SWISS ORDINANCE (EDI)

ON MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SR 817.023.21) DATED MAY 01, 2017

This ordinance regulates printings inks that are used for the printing of consumer goods surfaces that do not come into direct contact with food, in addition to other materials. These inks are described as preparations of colors and varnishes.

- Authorized substances including colorants are listed in Annex 10 part A or B (positive list).
- The regulation includes migration limits for certain substances and contains impurity criteria for aromatic amines and heavy metals.

Guidance for symbols:

A/B Classification of the basic colorant.

RECOMMENDATION BfR IX (FEDERAL INSTITUTE FOR RISK EVALUATION): COLORANTS FOR THE COLORATION OF PLASTICS AND OTHER POLYMERS FOR CONSUMER GOODS (FEBRUARY 1, 2015)

The BfR Recommendation is a German regulation for colorants for the coloration of plastics and other polymers for consumer goods. It defines purity requirements, such as limits for heavy metal content.

Guidance for symbols:

- The colorant fulfills the purity criteria with regard to heavy metal trace impurities according to Recommendation IX (BfR). Any contained additive(s) is (are) listed on the Regulation (EU) No. 10/2011.
- * The colorant fulfills the purity criteria with regard to heavy metal trace impurities according to Recommendation IX (BfR). The product contains one or several additive(s) not listed on the Regulation (EU) No. 10/2011.

EUROPEAN RESOLUTION AP (89)1 - ON THE USE OF COLORANTS IN PLASTIC MATERIALS COMING INTO CONTACT WITH FOOD

The European Resolution AP (89)1 deals with the use of colorants in plastic materials coming into contact with food. It defines purity criteria for colorants and sets certain maximum permissible content limits for

- Heavy metals
- Primary aromatic amines
- Polychlorinated biphenyls (PCB)

Guidance for symbols:

- The colorant meets the purity requirements of Resolution AP (89)1.
- The colorant does not meet the purity requirements of Resolution AP (89)1.

REGULATION (EU) NO. 10/2011 - ON PLASTIC MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

The Regulation (EU) No 10/2011 establishes specific requirements for the manufacture and marketing of plastic materials and articles intended to come into contact with food. This regulation lists permitted monomers and approved additives (Union list, Annex I) and sets overall and specific migration limits.

- Primary aromatic amines and certain defined metals shall not be released from the material and article in detectable amounts up to certain maximum limits.
- Colorants are exempted according to Article 5, paragraph (2) b) of the Regulation (EU) No. 10/2011 from being listed in the Union list. They are subject to national legislation according to Article 6, paragraph (2).
- The manufacturer of the end article has to ensure by suitable practical migration trials that the limiting value is not exceeded.

Guidance for symbols:

- Any contained additive(s) is (are) listed on the Regulation (EU) No. 10/2011.
- The colorant contains one or several additive(s) not listed on the Regulation (EU) No. 10/2011.

KEY REGULATIONS BY PRODUCTS

SHADE	PRODUCT	COLOUR INDEX	SWISS ORDINANCE	RECOMMENDATION BFR IX	EUROPEAN RESOLUTION AP (89)1	REGULATION (EU) NO 10/2011
	PV FAST YELLOW H9G	P.Y. 214	-	●	●	●
	INK JET YELLOW H2G	P.Y. 120	B	●*	●	○
	INK JET YELLOW 4G	P.Y. 155	A	●	●	●
	INK JET YELLOW 4GC	P.Y. 155	A	●	●	●
	TONER YELLOW 3GP	P.Y. 155	A	●	●	●
	INK JET YELLOW HG 01 VP 6252	P.Y. 180	A	●	●	●
	PV FAST YELLOW HG 01	P.Y. 180	A	●	●	●
	TONER YELLOW HG	P.Y. 180	A	●*	●	○
	NOVOPERM YELLOW P-HG	P.Y. 180	A	●*	●	○
	TONER YELLOW 5GXT	P.Y. 74	B	●*	●	○
	INK JET YELLOW 5GX-W	P.Y. 74	B	●*	●	○
	INK JET YELLOW 5GS	P.Y. 74	B	●*	●	○
	HANSA YELLOW 5GX 01	P.Y. 74	B	●*	●	○
	HANSA BRILLIANT YELLOW 5GX 03	P.Y. 74	B	●*	●	○
	NOVOPERM YELLOW P-M3R	P.Y. 139	A	●	●	●
	GRAPHTOL ORANGE RL	P.O. 34	B	●	●	●
	PV FAST ORANGE GRL	P.O. 43	A	●	●	●
	PV FAST ORANGE H2GL	P.O. 64	A	●	●	●
	PV FAST RED D3G	P.R. 254	B	●	●	●
	GRAPHTOL CARMINE HF4C	P.R. 185	B	●	●	●
	PERMANENT CARMINE FBB 02	P.R. 146	A	●	●	●
	PERMANENT RUBINE F6B	P.R. 184	B	●	●	●
	INK JET MAGENTA E5B 02	P.V. 19	A	●	●	●
	INK JET MAGENTA E7B	-	A	●	●	●
	INK JET MAGENTA E 02	P.R. 122	A	●	●	●
	TONER MAGENTA E 02	P.R. 122	A	●	●	●
	TONER MAGENTA E	P.R. 122	A	●	●	●
	PV FAST PINK E 01	P.R. 122	A	●	●	●
	INK JET MAGENTA E-S VP 6057	P.R. 122	A	●*	●	○
	PV FAST VIOLET RL	P.V. 23	A	●	●	●
	HOSTAPERM VIOLET RL 02	P.V. 23	A	●*	●	○
	HOSTAPERM VIOLET P-RL	P.V. 23	A	●	●	●
	PV FAST BLUE BG-NIP	P.B. 15:3	A	●	●	●
	HOSTAPERM BLUE BT-617-D	P.B. 15:4	A	●*	●	○
	HOSTAPERM GREEN GNX-C	P.G. 7	A	●	●	●
	COPY CHARGE N4P	-	A	●*	●	○

●* The colorant fulfills the purity criteria with regard to heavy metal trace impurities according to Recommendation IX (BfR).
The product contains one or several additive(s) not listed on the Regulation (EU) No. 10/2011.

● The product complies with the requirements/criteria of Recommendation BfR IX,
European Resolution AP (89)1 and/or Regulation (EU) No. 10/2011.

○ The colorant contains one or several additive(s) not listed on the Regulation (EU) No. 10/2011.

ABBREVIATIONS

AP:

Partial Agreement in the social and public health field

BFR

Bundesinstitut für Risikobewertung
(The German Federal Institute for Risk Assessment)

EDI

Eidgenössisches Departement des Inneren
(Federal Department of Home Affairs, Switzerland)

EU

European Union

PCB

Polychlorinated biphenyls

REACH

Registration, Evaluation, Authorisation and Restriction
of Chemicals



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