

PACKAGING INKS FOR FOOD CONTACT MATERIALS (FCM)

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1. EUROPEAN FOOD CONTACT LEGISLATION

There is currently a large amount of legislation in Europe relating to Food Packaging.

The main pieces of legislation concerned are:

- Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food.
- Commission Regulation (EU) No. 10/2011 and amendments relating to plastic materials and articles intended to come into contact with foodstuffs.
- Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food.

The first two pieces of legislation specifically exclude printing inks, although the dried print will come into scope of 1935/2004 in regards to Article 3 which states:

Materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could:

(a) endanger human health;

or

(b) bring about an unacceptable change in the composition of the food;

or

(c) bring about a deterioration in the organoleptic characteristics thereof.

In addition these two pieces of legislation cover materials which are intended for direct food contact, and most inks and coatings supplied by Flint Group are not intended to come into such contact.

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1A. GMP AND PRINTING INKS DESIGNED FOR FOOD CONTACT MATERIALS (FCM)

The ink manufacturer has the responsibility under the GMP Regulation (3 above) to manufacture the inks under GMP and to formulate products which – if correctly applied – should allow the other members of the packaging chain – i.e. converter, packer/filler etc. to meet their responsibilities under the legislation.

This is to confirm that Flint Group packaging inks which are designed for FCM are manufactured in accordance with the EuPIA Good Manufacturing Practice.

Flint Group will also disclose - under a completed Non-Disclosure Agreement in some cases - relevant adequate information on the components in the ink. The substances will be any that are listed in the Plastics Regulation (EU) No. 10/2011 [and amendments], the Swiss Ordinance 817.023.21 Annex 2 or 10, any Dual Use substances and all other known low molecular weight substances, with potential to migrate, including all volatile substances.

Such a disclosure will be supplied in the form of a Statement of Composition (eSoC).

2. BACKGROUND AND RAW MATERIALS

It is a general recommendation that pigmented inks are not supplied for direct food contact, and that there should be a barrier between ink and food. Flint Group agree with this, and only supply such pigmented products for direct food contact when made outside by operations with suitable manufacturing conditions, and using materials suitable registration from organisations such as the F&DA in America.

The suitability of our inks for use on the non-contact side of primary food packaging and/or indirect food packaging use, with the above proviso in mind, is based on the following factors:

a. *Known toxic materials*

National members of the European Trade Association -The European Printing Ink Association [EuPIA], (part of CEPE (Conseil Européen de l'Industrie des Peintures, des Encres d'Imprimerie et des Couleurs d'Art), to which Flint Group are affiliated, will not supply inks which contain materials which are specified in the selection criteria of the EuPIA Exclusion Policy.

For many years now, the Industrial Trade Associations have monitored the ingredients used in the manufacture of inks, and where there has been concern over suitability for food use, the materials have been barred - often on a unilateral basis, even though no legal constraint existed. This is done in the light of the general approach of being responsible manufacturers of materials connected with the food industry.

The result of this was an Exclusion List, issued originally by the British Coatings Federation, containing a list of materials banned from use. This list was adopted by EuPIA and with the progression of the REACH legislation EuPIA has superseded the list with an exclusion policy. A copy of the **Exclusion Policy for Printing inks and Related Products** is available from the EuPIA website – <http://www.eupia.org>.

Substances and mixtures classified in the following hazard classes/categories, shown with their respective hazard statement codes, are excluded as raw materials for the manufacture of printing inks and related products supplied to printers.

b. *Other materials*

The substances used for the production of inks and varnishes for the printing of the non-contact side of food packaging are listed in Annex 2 or 10 of Swiss Ordinance 817.023.21, as updated on October 15th, 2022.

A number of these substances are listed in these annexes under a generic description or covered by a generic group rather than individually identified.

c. *Pigments and dyes*

This is an area which is not as yet covered by positive listings such as the F&DA and EU Directives.

Accordingly, the main concern has been towards the heavy metal contaminants, which has a direct effect on the suitability of our materials for uses governed by the specifications of:

- The Council of Europe Resolution AP(89)1 or national recommendations on the use of colorants in plastic materials intended to come into contact with food.
- TPCH (Toxics in Packaging Clearing House – previously CONEG) Regulations in the United States, and, in particular, the Essential Requirements of the **EC Packaging and Packaging Waste Directive (94/62/EC)** in the European Union Countries.

The latter two regulations lay down strict limits for the total levels of four heavy metal contaminants:

- Lead, Mercury, Cadmium and Chromium VI.

As a general rule the pigments and dyes used in packaging inks fall well within the limits set out by the above regulations.

The only exceptions to this are for Barium where one class of pigment - the Lake Red C's - and the Barium Sulphate extenders, will be outside the Resolution limits. Accordingly, when it is specified that these regulations are to be met, inks are formulated not to contain these pigments or extenders.

It should be noted that these materials are considered fully suitable for use on the non-contact side of food packaging.

3. SUMMARY

Accordingly, Flint Group take all reasonable precautions to ensure that the products supplied, and the raw materials on which they are based, are suitable for use in inks to be supplied to the non-contact side of food packaging.

As members of the European Printing Ink Association (EuPIA) we confirm that we follow the EuPIA Guideline on Printing Inks applied to Food Contact Materials.

However it is the ultimate responsibility of the downstream members of the Packaging Chain to ensure that the final package is in compliance with the Annex of GMP Regulation 2023/2006, and hence in compliance with framework Regulation (EU) No 1935/2004.

In addition, whilst it is not possible to guarantee against contamination, the use of normal industrial hygiene precautions during the manufacture of our inks is likely to result in a minimal chance of any contamination occurring. These practices are in line with the Good Manufacturing Legislation as set out in §1A above.

Obviously, once the inks have left our premises and control, the responsibility to ensure that there is no contamination lies with the converter.

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