GMP ("Good Manufacturing Practice")

Printing Inks for Food Contact Materials

© maslakhatul
stock.adobe.com

Content

[1]This Good Manufacturing Practice (GMP) has been prepared by the European Printing Ink Association (EuPIA), a sector of the European Council of Paint, Printing Ink and Artists' Colours Industry (CEPE) to assist in controlling food safety hazards in the design and manufacture of inks, varnishes and coatings designed to be printed onto Food Contact Materials (FCM inks), and formulated for use on either the non-food contact or the food contact surfaces of food packaging and articles intended to come into contact with food.

Products developed and manufactured in compliance with this GMP are supporting manufacturers of food contact materials in supplying products compliant to the applicable legislation in Europe for materials and articles intended to come into contact with food such as the Framework Regulation (EC) No 1935/2004, and GMP Regulation (EC) No 2023/2006.

Source[1]:https://www.eupia.org/key-topics/food-contact-materials/good-manufacturing-practice-gmp/

1. What does „GMP" stand for?

GMP ("Good Manufacturing Practice") is a part of quality assurance used in the pharmaceutical and food industries to ensure that products are manufactured in accordance with established quality standards. GMP requirements are defined in various guidelines and regulations and apply to the manufacture, packaging, storage, and documentation of products to ensure their quality, safety, and efficiency.

2. What does it have to do with printing inks?

There are no legal GMP regulations for printing inks themselves. But since printed end products, e. g. food contact materials, may be subject to legal GMP requirements, the manufacturers of these products also require additional information/quality standards from the printing ink.

3. What is the difference: GMP vs. low migration?

GMP refers to the adherence to predefined quality standards to ensure consistent, defined quality. GMP is therefore a "quality statement" and not a "conformity statement". The conformity of the printed end product depends not only on the ink itself, but also on various printing parameters (substrate, drying/curing conditions, etc.). This must therefore always be checked individually. The term "low migration" ("only very few substances migrate") is therefore confusing and should be questioned, because it suggests conformity for the printed end product, which may only apply under very specific application conditions. In addition, "low migration" does not say anything about consistent quality in case of doubt.

We therefore advertise our printing inks for this area of application as "compliant with EuPIA GMP".

4. How is GMP implemented at Marabu?

With the Ultra *Pack* UVFP and Tampa® *Tex* TPX series, we offer two series that are produced in accordance with the EuPIA GMP requirements for indirect food contact.

This includes not only raw material selection and incoming raw material control, but also the documentation of the production steps, the quality control of each production batch up to the determination of the customers who receive a GMP-compliant product.

5. What does it take for a GMP-compliant product?

With the printing ink, we supply <u>one</u> of three building blocks for a GMP-compliant end product; the final conformity can only be determined by simultaneously considering the process conditions and the substrate. In order to produce a compliant food contact material, close cooperation with the manufacturer of the FCM printing ink and the manufacturer of the food contact material is therefore necessary.

It is therefore essential that the application is known before a recommendation can be made for a printing ink. Recommendations for FCM inks may only be made by specially trained personnel.

6. Procedure

Due to legal requirements and traceability, the GMP compliance applies to **all TPX and UVFP standard shades produced and filled at Marabu Germany. For UVFP, this has already been the case for several years, and for TPX from week 18/2023 (batch code 318).**

If you need a confirmation of conformity for a TPX or UVFP custom ink, our contacts mentioned under point 8 will retrieve specific information on the basis of a questionnaire.

After a suitability assessment for the intended use, a suitable procedure can be recommended by our product safety department.

Provision of the following documents by Marabu:
- Technical Data Sheet
- Safety Data Sheet (SDS)
- Regulatory statement
- Formulation transfer to test institutes (with NDA)

Please note that this procedure is associated with significant additional costs, and therefore only appropriate in the case of a mandatorily required confirmation of conformity.

Customers who use TPX or UVFP, but do not require GMP confirmation according to EuPIA for FCM (Food Contact Material), receive custom inks **without confirmation of conformity** as **UVFP-N** or **TPX-N** (N = NON-GMP).

7. Exceptions

For the GMP-compliant products listed in the respective Technical Data Sheet, a particularly high production standard is implemented, which, among other things, also represents a cost factor due to extensive analyses. This is simply not feasible with many raw materials used in custom or effect inks.

8. Contact

Advice and support is provided by our Sensitive & Packaging segment experts:

Packaging/Screen printing:
Pascal Iffland: if@marabu.com
Alexander Suckfüll: suc@marabu.com

Sensitive/Pad Printing:
Sabrina Brenneisen: kur@marabu.com

All statements made here refer exclusively to standard colour shades. For custom inks, the described features may deviate.

Marabu GmbH & Co. KG · Phone: +49 7141 6910 · info@marabu-inks.com · www.marabu-inks.com   Page 2/2