EuPIA
European Printing Ink Association
A sector of CEPE aisbl

Good Manufacturing Practices for the Production of Packaging Inks formulated for use on the non food contact surfaces of food packaging and articles intended to come into contact with food

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PREFACE

Over recent years, the National Association members of the European Printing Ink Association (EuPIA), a sector of the European Council of Paint, Printing Ink and Artists' Colours Industry (CEPE), have employed a common Exclusion List of raw materials that are avoided for formulating, manufacture and supply of printing inks. This has been recognised as a fundamental part of Good Manufacturing Practices (G.M.P.).

This Exclusion List has now been further enhanced by the production of a Guideline on Printing Inks applied to the non-food contact surface of food packaging materials and articles. This Guideline sets out a Selection Scheme for Packaging Ink Raw Materials which further specifies requirements which such Raw Materials must meet in terms of purity, migration and toxicological properties.

The EuPIA Technical Committee has decided that, as a contribution to customer awareness, there was a need for a more specific G.M.P., especially aimed at packaging inks applied to the non food surface of packaging and articles. This would assist the harmonisation of the multinational practices of many printers, their packaging requirements and standards.

The National Associations have now fully endorsed this revised version of the G.M.P. for inks for food packaging and recommend its adoption from January 2006.

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1. Scope and Objective

These Good Manufacturing Practices (G.M.P.) apply to the manufacture of printing inks, primers, coloured lacquers and varnishes (hereafter referred to as "food packaging inks") intended for use only on the non food contact surfaces of food packaging and articles.
Procedures for formulation, production and control are defined in order to warrant that food packaging inks:

- comply with existing regulations and/or generally accepted requirements for packaging and articles intended to come into contact with food.
- are fit for the purpose intended.
- meet agreed customers' end use specifications.

2. Controls

2.1 *Manuals*

Detailed operational manuals cover receipt of orders, formulation, manufacture and product delivery to agreed standards. Recording systems ensure that each stage can be verified for correct action.

2.2 *Production Instruction Documents*

An instruction document (batch card) is issued for each batch of printing ink manufactured. This details the materials, quantities and equipment to be used and highlights any specific precautions to be followed. Each stage is recorded.

2.3 *Product Test Specifications*

Product test specifications exist for each food packaging ink manufactured. They list the tests which are required during manufacture and on completion, to ensure the batch meets the required specification and is fit for intended use according to agreed tests. The specification contains, where appropriate, the tolerances for each test.

3. Quality Review Procedure

In the event of non-compliance at any stage of the process or a confirmed complaint, a procedure exists to take corrective and preventative action to find the cause, rectify the problem, and if necessary make the appropriate improvement(s) to the manuals or other controls to prevent a repetition.
A person is appointed to accept responsibility for ensuring that any non-compliance issue is dealt with, and corrective action completed

4. Personnel and Training

4.1 *Commitment*

The entire workforce, involving all levels of management is committed to the objectives of G.M.P..

4.2 *Training*

Training programmes and facilities are established to ensure that all personnel are fully aware of their functions and responsibilities and are competent to carry them out.

5. Raw Material Controls

5.1 *Objective*

G.M.P. requires complete co-operation with the suppliers of raw materials and knowledge of the needs of the customer. Raw materials are carefully selected to ensure that the components of the food packaging inks comply with the requirements of appropriate national legislation, are suitable for quality and are within agreed tolerances.

5.2 *Suitability*

Raw materials are selected in line with the above-mentioned EuPIA Guideline on Printing Inks for the non-food contact surface of food packaging materials and articles, so that, when food packaging inks are correctly applied, the printed surface should not:

- endanger human health.
- cause deterioration in the organoleptic nature of the packed foodstuff.
- bring about an unacceptable change in the composition or quality of the packed foodstuff.

Substances that are excluded according to the raw materials selection criteria of the “EuPIA Exclusion List for Printing Inks and Related Products” are not used.

5.3 *Identification*

A name, reference number and batch or delivery number identify each raw material, so it can be traced, as required by Regulation (EC) No. 1935/2004 of the European Parliament and of the Council of 27 October 2004.

5.4 *Specifications*

Each raw material has a specification agreed between the supplier and the food packaging ink manufacturer. The specification includes physical and chemical properties to maintain agreed ink manufacturing quality and print end-use technical requirements.

5.5 *Conformity*

Where appropriate, raw materials are tested in house or alternatively are supported by a certificate of conformity from the raw material supplier, relating to the agreed specification. In some instances pre-delivery samples representing the batch may be submitted to the ink manufacturer for special tests prior to the delivery being accepted.

5.6 *Traceability*

Where possible, traceability of a batch of raw materials is achieved by the delivery / batch reference numbers throughout the system.
If batch referencing is not possible an alternative system has to be put in place.

5.7 *Storage*

Raw materials are stored under conditions to prevent contamination or deterioration. Rejected materials should be clearly marked as such.

5.8 *Usage*

Raw material stocks are rotated and used on a first-in first-out basis.

6. Formulation

The following parameters are considered when formulating food packaging inks:

- Type of substrate and material combinations
- Type of foodstuffs to be packed
- Type of printing processes and printing equipment
- Package-forming and filling processes
- End-user specifications
- Compliance to health, safety and consumer protection regulations
- Compliance with environmental policies for printing, manufacturing processes and end-use.

Food packaging inks are formulated such that, when appropriately applied:

- they have the necessary adhesion of the dry layer to the substrate and resistance to physical and chemical stress,
- they are suitable for the method of application and for subsequent converting processes,
- they have the binder/colourant combination which will meet product resistance specifications such as ISO standards or other agreed end use specifications,
- they will have no visible transfer on the reverse side of printed matter.
- they will cause no deterioration of the organoleptic nature of the packed foodstuff,
- they will both minimise potential migration through the substrate or the set-off from the printed outer side to the food contact surface in the stack or the reel,
- they will allow compliance of the final product with the existing legal provisions.

7. Production

7.1 *Objective*

To convert raw materials into products specified to meet the customers' requirement.

7.2 *Manufacturing Instruction Document*

Manufacturing instructions are issued and followed for each batch, giving details of the raw materials, the quantities and the equipment to be used. Critical parts of the process are recorded and checked by the operator.

7.3 *Manufacturing Formulation*

Only raw materials that have passed the quality control procedures according to 5.5 are used in quantities and proportions necessary to obtain the quality of the product.

7.4 *Equipment*

The equipment used should be suitable to manufacture the products required and be maintained in good repair; clean and - where necessary - calibrated. Maintenance documentation is established.

8. Quality Control

8.1 *Objective*

To carry out laboratory and manufacturing tests on food packaging inks produced to ensure that the products supplied to the customer are fit for application and end use, and conform to customer specifications.

8.2 *Production Quality Control*

Testing of food packaging ink samples at selected stages of the process is carried out in order to establish whether the product is meeting the required quality standard. A procedure is set up for the production personnel to adjust the process or product within the specified limits when necessary.

8.3 *Testing*

Products are tested to meet specifications established at the formulation stage. Some additional test methods may be agreed with customers.

8.4 *Test Equipment*

All measuring equipment is tested and / or calibrated where appropriate to a schedule to ensure that the test results are accurate.

9. Product Information

9.1 *Identification and traceability*

A descriptive title or a trade name, reference number and specific batch number, identifies each product.

9.2 *Conformity*

Where appropriate, each delivery of food packaging inks can be supported by a statement of conformity, confirming that it meets the agreed specification.

9.3 *Data Sheets*

Each product has supporting product data sheets detailing relevant chemical, physical and safety data, and suitable end uses and methods of application.

10. Packaging

10.1 *Specification*

Packaging is selected to protect the food packaging ink during shipment and storage and conforms to the appropriate national, European and UN requirements for the nature of the product packed and the means of transport.

10.2 *Cleanliness*

New containers are inspected for cleanliness. Returned containers are inspected and cleaned, if necessary, to avoid any contamination with other products or foreign materials.

10.3 *Accurate Filling*

Filling controls are accurate within legal measuring limits. All weighing equipment is examined for accuracy, re-calibrated if necessary and frequently inspected.

10.4 *Labelling*

Each container has the minimum following information on labels:

- Identification of the producer

- Reference number and description of product
- Batch number
- Net weight
- Health, safety and transport information as required.

11. Storage

All products (including raw materials) are stored in conditions to prevent, as far as possible, any deterioration of the material. Where appropriate a procedure exists to test stock that may have been held for some time to ensure it has not drifted from specification. Rejected stock is clearly marked as such and isolated to avoid accidental use.

12. Delivery

All products are delivered in clean and clearly labelled suitable containers.

13. In-plant operations

Many inks are now blended at converter plants from basic constituents (concentrated coloured bases and additive varnishes), often through automated dispensing equipment.

When inks are manufactured by this procedure, the resultant inks have a reference number, description and batch number recorded, and the batch numbers of the constituents used to produce the finished inks also recorded.

If inks are returned from the print operation in their original state, they should be booked into stock under the relevant description and batch number.

Inks returned in a modified state should be checked for suitability for re-use. If found suitable then they are issued with a new description, reference & batch number..

If these modified inks are re-used or re-handled, the modifications should be recorded, the product tested and this new product labelled accordingly. Full traceability is required in the normal way.