



Good Manufacturing Practices
for the production of UV/EB resins for coatings and inks
intended for use on the non-food-contact surfaces of food
packaging

Cefic UVEB

June 2015



Chemistry making a world of difference

European Chemical Industry Council
Avenue E. van Nieuwenhuysse 4 B - 1160 Brussels Belgium
Tel: +32 2 676 72 88 Fax: +32 2 676 73 47 jwi@cefic.be www.cefic.org



Preface

This guidance document has been produced by members of Cefic UVEB. Its aim is to provide guidance on the good manufacturing practices in the manufacture of UVEB resins, which are designed for the formulation of UVEB coatings and printing inks used on the non-food-contact surfaces of food packaging.

This guidance was developed in line with the GMP guidelines of the European Coatings and Printing Inks associations (EuPIA GMP: http://www.eupia.org/uploads/tx_edm/2009-03-01_corr_GMP_Packaging_Inks_March_2009.pdf and CEPE GMP: http://cepe-myeteam.eudata.be/EPUB//easnet.dll/GetDoc?APPL=1&DAT_IM=1037C0&DWNLD=100802_GMP_Can_Coatings.doc)

This guidance document was developed to reflect the strong commitment of the European UVEB resin industry to comply with food contact and consumer safety requirements. The use of this guide is voluntary but strongly recommended.

Good Manufacturing Practices
for the production of UV/EB resins for coatings and inks
intended for use on the non-food-contact surfaces of food
packaging

CONTENTS

1.	Regulatory background	5
2.	Objective	5
3.	Scope.....	6
4.	Definitions.....	6
5.	Quality Management system and documentation	6
5.1	Quality Management system.....	6
5.2	Manuals.....	7
5.3	Hazard Analysis and identification of critical control points	7
5.4	Hazards to be Considered.....	7
5.5	Production Instruction Document.....	8
5.6	Product Test Specification	8
5.7	Non conformity management.....	8
5.8	GMP audit.....	8
5.9	Traceability.....	8
6.	Personnel and Training.....	9
6.1	Commitment	9
6.2	Training.....	9
7.	Development and composition of UV/EB resins for food packaging.....	9
8.	Raw Material Controls.....	10
8.1	Objective.....	10
8.2	Identification.....	10
8.3	Specification and certification	10
8.4	Conformity	10
8.5	Traceability.....	10
8.6	Storage.....	11
8.7	Recycled and recovered materials.....	11
9.	Production.....	11
9.1	Manufacturing Instructions.....	11
9.2	Equipment.....	11
9.3	Cleanliness	11
10.	Packaging.....	12

10.1	Specification.....	12
10.2	Cleanliness.....	12
10.3	Accurate Filling.....	12
10.4	Labelling.....	12
11.	Quality Control.....	13
11.1	Objective.....	13
11.2	In-process Quality Control.....	13
11.3	Finished Product Testing.....	13
11.4	Test Equipment.....	13
12.	Warehousing.....	13
13.	Product Information.....	14
13.1	Identification.....	14
13.2	Food packaging compliance Documentation.....	14
13.3	Shelf life.....	14

1. REGULATORY BACKGROUND

The Framework Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food requires that such materials and articles, including coated and printed materials, are manufactured in compliance with good manufacturing practice. The application of good manufacturing practice should ensure that such materials 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 2006, the European Commission further emphasised the importance of having Good Manufacturing Practice regimes in place via Commission Regulation (EC) No. 2023/2006 on “good manufacturing practice for materials and articles intended to come into contact with food.”

It is considered that the utilisation of appropriate manufacturing processes and hazard analysis and control systems, under the umbrella of a quality management system such as ISO 9001 should satisfy the requirements of Good Manufacturing Practice laid out in this Regulation.

2. OBJECTIVE

This GMP recommendations has been produced in order to provide details on the processes and controls that are considered appropriate for the manufacture of UV/EB resins in order to allow downstream users of these resins to fulfill their obligations defined in the Framework Regulation (EC) No. 1935/2004 and in the Regulation (EC) No 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.

More specifically, procedures for the development, the production, the control, the packaging and the warehousing are defined in order to warrant that food packaging coatings and inks formulated with UVEB resins:

- comply with existing regulations and/or industry requirements for packaging and articles intended to come into contact with food.
- are fit for the purpose intended (suitable purity).
- meet agreed customers’ and end use specifications.

It should be noted that this guide should not be considered as a set of regulations in itself and does not excuse manufacturers of coatings, inks or the articles onto which they are applied from their obligations in meeting all relevant regulations relating to their products.

3. SCOPE

These Good Manufacturing Practices apply to the production of UV- or EB-curable resins which are designed and/or promoted for the formulation of coatings, inks and/or overprint varnishes for the non-food-contact surfaces of food packaging.

4. DEFINITIONS

Good Manufacturing Practice (G.M.P.) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimise the risks involved in any production of resins designed for food contact that cannot be eliminated through product design. The main risks include:

- unexpected contamination of products, causing damage to health,
- incorrect labels on containers, which could mean that customers could receive the wrong product.

G.M.P. covers all aspects of production, from the starting materials, premises and equipment to the training and personal hygiene of staff.

5. QUALITY MANAGEMENT SYSTEM AND DOCUMENTATION

5.1 QUALITY MANAGEMENT SYSTEM

Good Manufacturing Practices are embodied in a Total Quality Management System as described in the ISO 9001 standard.

However, it is important to understand that an ISO 9001 quality management system alone is not enough to achieve food contact G.M.P. Indeed, the quality management system must be set up in such a way that the targeted product quality is suitable for food contact application and not only for the general industrial uses. The difference lies in the control of the product purity/quality which is usually not needed for general industrial application since they focus mainly on the technical performance. The hazard analysis (see point 5.3) determines if and what specific processes and controls are needed for achieving food contact G.M.P.

5.2 MANUALS

Detailed written procedures exist for each process step, from the development of resins designed for food contact, to receipt of the order for the products, through manufacture to delivery of the coatings that could affect the quality of the finished product.

There are systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process – every time a product is made.

5.3 HAZARD ANALYSIS AND IDENTIFICATION OF CRITICAL CONTROL POINTS

The establishment of GMP requires an analysis of the potential hazard in the entire process and the identification of critical control points. An approach inspired from the Hazard Analysis and Critical Control Process (HACCP) could be used. This consists in:

- conducting a hazard analysis of the product and its production process
- Identifying critical control points. A Critical Control Point is a step at which control can be applied and is essential to prevent the contamination or reduce it to an acceptable level. It is recommended that individual Critical Control Points are identified by local risk assessment of each process.

It has to be noted that a full HACCP implementation and certification (ISO 22000) is not needed for the production of UV/EB resins and therefore it is not really recommended as it is heavy to put in place and to maintain.

All stages of the process, from raw materials and their storage and handling, resin production, filtration, filling into containers, storage and delivery, including all plant engineering and maintenance aspects, should be covered.

This analysis need not be third-party approved but shall be part of, or linked to, the plant quality management system.

5.4 HAZARDS TO BE CONSIDERED

All potential sources of contamination of the resins should be considered in hazard analysis, including:

- chemicals (raw) materials that are not covered under the requirements of EU “Framework” Regulation No. 1935/2004, Commission Regulation (EU) No 10/2011 (or subsequent amendments) or the USA FDA regulation 175.300.
- chemicals (raw) materials that are covered under the above-mentioned regulations but which may be present in a not specified concentration and may therefore exceed the limits set forth in the regulations (e.g. maximum quantities, specific migration limits)
- chemical products not associated with the formulae of coatings designed to come into contact with food – e.g. lubricating oils, greases, sprays, etc.

- biological or microbiological entities or products - e.g. algae in waterborne UV/EB products
physical articles - intact or damaged – e.g. pens, pins, knives, blades, broken glass, tooling swarf, etc

5.5 PRODUCTION INSTRUCTION DOCUMENT

An instruction document (e.g. batch card) is issued for each batch of resin manufactured. This details the materials, quantities and equipment to be used and highlights any specific precautions to be followed.

5.6 PRODUCT TEST SPECIFICATION

Product Test Specifications exist for each resin manufactured. They list the tests, which are required during manufacture and on completion to ensure the batch meets the resin technical and purity specifications and contain, where appropriate, the tolerances for each test. The specifications for resins used in food packaging applications might be more specific taking into account impurities and possible contaminants

5.7 NON CONFORMITY MANAGEMENT

In the event of a non-compliance at any stage of the process or a complaint, a procedure exists to find the cause, rectify the problem and if necessary make the appropriate improvement(s) to the procedures or other controls to prevent a repetition. A person is appointed who is independent of the production and quality control functions to accept responsibility for ensuring that any non compliance issue is dealt with and that corrective actions are completed.

5.8 GMP AUDIT

Implementation and achievement of GMP is monitored by using a “GMP-Audit Checklist” and by performing internal audits on a regular basis, for instance as part of the normal quality management audits. Corrective measures are identified to correct any failure to achieve GMP. These are implemented without delay.

5.9 TRACEABILITY

The traceability of materials is required at all stages. Raw materials and finished products are identifiable by an appropriate system such as labelling, or relevant documentation and information. Where possible, traceability of materials (including raw materials) is achieved by the delivery / batch reference numbers throughout the system. If batch referencing is not possible, e.g. in the case of bulk storage of raw materials, an alternative system has to be put in place in order to achieve as much traceability as possible without becoming an excessive burden for the business.

6. PERSONNEL AND TRAINING

6.1 COMMITMENT

The entire workforce involved in the production of food contact resins, including all levels of management is committed to the objectives of G.M.P.

6.2 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.

7. DEVELOPMENT AND COMPOSITION OF UV/EB RESINS FOR FOOD PACKAGING

The resins designed and/or promoted for food packaging applications should be formulated such that, when properly applied and used,

- they should cause no deterioration of the organoleptic nature of the packed foodstuff,
- they should allow compliance of the final product with the existing legal provisions by minimizing transfer from the coated/printed surface to the food contact side .

The composition of the resins designed and/or promoted for food packaging applications should be properly determined, documented and assessed. This includes

- The documentation of the impurities of the raw materials used for the production of the UV/EB resin based on supplier information (SDS, certification, specification etc.)
- An analysis of the resin by-product(s) and its subsequent documentation
- A safety assessment of all resin components, not limited to monomers and additives, but including all components of the resin such as polymerization aids, impurities of the raw materials and by-products. However it has to be noted that the resin manufacturer can only assess the resin composition and not the coating formulations nor the final coatings which are unknown to him. Moreover, it is not always possible for the resin manufacturer to assess fully the impact of components which are consumed (e.g. acrylated impurities) or generated during the curing (e.g. photoinitiator by-products) because the coating/ink formulation and curing conditions which are outside the resin producer's control have a large impact on the result. In these cases, the components that have not been fully assessed shall be mentioned to the customers and the safety assessment shall be explicitly delegated to the coating/ink formulator or producer by means of the Compliance Documentation (see point 13.2).

Specifications are set up at the development stage in order to ensure that the resins produced will consistently meet the technical and purity requirements.

8. RAW MATERIAL CONTROLS

8.1 OBJECTIVE

G.M.P. requires co-operation with the suppliers of raw materials and knowledge of the needs of the customer. Although standard industrial raw materials are generally used, they are carefully selected to ensure that each ingredient of the food contact resin is of a suitable quality (purity) for the product and is within agreed specifications.

8.2 IDENTIFICATION

A name, reference number and batch or delivery number identify each raw material, so it can be traced, as required by Regulation 1935/2004 of the European Parliament.

8.3 SPECIFICATION AND CERTIFICATION

Each raw material has a specification, accepted by the resin manufacturer. The specification should include physical and chemical properties to maintain the agreed resin manufacturing quality and end-use technical requirements.

Additional certification may be needed on top of the specifications, to ensure that the raw material purity is suitable for its use in the manufacture of food contact resins. Special attention shall be paid to the substances of concern such as the Carcinogenic, Mutagenic, Toxic to Reproduction and Neurotoxic substances (CMRN) which may have very low tolerable daily intakes. Indeed such substances may endanger human health even when present at traces amounts, below the threshold for declaration in the Safety Data Sheet. However, some CMRN substances that have been evaluated and cleared by the authorities (e.g. Listed in Annex I of the Plastics Regulation No 10/2011) may be tolerated in the limits of their regulatory clearance.

8.4 CONFORMITY

Raw materials are only taken from approved suppliers and are delivered in compliance with specification, or variance agreed by documented concession.

Compliance with the specifications is supported by a certificate of conformity from the raw material supplier or tested in-house

8.5 TRACEABILITY

Traceability of a batch of raw material is achieved by using the name/reference number and a delivery/batch number throughout the system. If batch referencing is not possible an alternative system is put in place.

8.6 Storage

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

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

8.7 RECYCLED AND RECOVERED MATERIALS

The use of recycled and recovered materials is desirable from environmental and economical perspective but should be carefully assessed to pose no risk to human health and kept under control.

9. PRODUCTION

9.1 MANUFACTURING INSTRUCTIONS

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.

9.2 EQUIPMENT

The equipment used is suitable to manufacture the products required. It is kept in good repair with a documented inspection and maintenance schedule appropriate to the particular piece of equipment.

All measuring, metering or weighing equipment that are used as part of the production process is subject to calibration checks at defined intervals.

9.3 CLEANLINESS

The use of plant dedicated to the manufacture of food contact resins is desirable but not essential. Cross-contamination between successive batches of different products should be avoided or, when not technically/ economically possible, it shall be reduced to a minimum, assessed to pose no risk to human health and kept under control. This also applies to the cross-contamination between successive batches of food contact resins of different composition since the contaminating resin may have different technical properties (impact on the quality of the final ink/coating) and also different migration limits.

Examples of means to avoid cross-contamination:

- Dedicated plants

- Cleaning process (pay attention to the cross-contamination with the cleaning products)

Example of means to decrease and control cross-contamination

- Production in campaigns
- Sequencing rules

10. PACKAGING

10.1 SPECIFICATION

The packaging is selected to protect the resin during shipment and storage and complies with legal requirements for the nature of the product packed and the means of transport.

10.2 CLEANLINESS

Containers are individually inspected for cleanliness prior to fill and are sealed as soon as possible after filling.

Returned multi-use containers are cleaned to remove residual product and any contamination from foreign materials and are inspected before re-use.

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 carries labels showing, where appropriate: -

- Identification of the supplier of the UV/EB resin
- Reference number and product description (trade name where appropriate)
- Batch number
- Safety Labelling in accordance with national and international regulations.
- Net Weight

11. QUALITY CONTROL

11.1 OBJECTIVE

Laboratory tests on the resin in-process and on the resin finished products are carried out to ensure that resins supplied to the customer are fit for application and end use and conform to agreed customer specifications.

11.2 IN-PROCESS QUALITY CONTROL

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

Testing is not limited to the laboratory or laboratory personnel. It may be carried out by any trained authorised person at a convenient location.

11.3 FINISHED PRODUCT TESTING

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

11.4 TEST EQUIPMENT

All test equipment is tested and/or calibrated according to a schedule to ensure that the test results are accurate. The test information is recorded.

12. WAREHOUSING

Raw materials and finished resins are stored in conditions to prevent any deterioration of the material.

Unapproved or rejected raw materials and finished products are quarantined. A procedure must exist to prevent their mix up with approved materials. They are (preferably) kept in a separate designated area.

Raw Materials are used and finished products are sold on a first-in-first out (FIFO) basis.

13. PRODUCT INFORMATION

13.1 IDENTIFICATION

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

When the same resin is produced in different qualities, some being suitable for food packaging and others not, this shall be made clear through a difference in the product name.

13.2 FOOD PACKAGING COMPLIANCE DOCUMENTATION

On request of the customer, the resin supplier will provide written documentation (Declaration of Compliance, Statement of Composition or any equivalent written document) setting out the information which a customer will need to ensure compliance with Regulation (EC) No 1935/2004, and food contact materials covered by specific measures, such as Regulation (EU) No 10/2011 and Directive 2007/42/EC. Where applicable, the documentation should include information about the presence of ingredients for which the compliance and safety assessment could not be completed (substances subject to migration limits, substances not assessed etc.), cf. chapter 7.

Such documentation shall be available (on request) for all products designed and/or promoted for food packaging applications but is not mandatory for other products designed / promoted for general industrial uses.

The Safety Data Sheets provided in compliance with REACH (Regulation (EC) No 1907/2006) are not considered to be sufficient for customers to ensure compliance with Regulation (EC) No 1935/2004 and other food packaging regulations.

13.3 SHELF LIFE

The shelf life of the resin shall be communicated to the customers.