



**FAKOLITH**  
chemical systems

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**PRESS RELEASE**



Management  
System  
ISO 9001:2015

www.tuv.com  
ID 9105043000

All Fakolith paints and varnishes suitable for direct and indirect contact with food, comply with the new regulation EU 2018/213, since 2013:

**EU 2018 / 213** **06.Sept.2018**  
**New Regulation**  
**FAKOLITH**  
chemical systems  
**This has changed!**  
**New migration limit for BPA**  
**Bisphenol-A is 0,05 mg/Kg**  
**Paints and Varnishes**  
**are under EU 10/2011**

**COMMISSION REGULATION (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials.**

<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32018R0213&from=EN>

The new regulation REGULATION (EU) 2018/213 OF THE COMMISSION that modifies the regulation (EU) 10/2011, was been published as a draft a long time ago. Fakolith, to formulate their paints and food contact varnishes, for the peace of their customers, not only considers the regulations in force, but also the drafts of future international regulations, both EU and FDA, as well as with the international trend. So that, the application and use of our paints and varnishes, meets the highest legislative requirements for today and the future.

All the Fakolith FoodGrade range of paints and varnishes for food contact, epoxy, polyurethane, acrylic or miscellaneous, comply with Regulation REGULATION (EU) 2018/213. Everything is indicated in the Compliance Declaration of each product, being endorsed by the results of tests done in accredited independent laboratories:

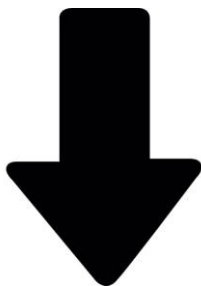
This regulation is very important, **as from September 6, 2018**, it will no longer be possible to introduce paints and varnishes for direct contact with foods on the market that do not comply with Regulation 2018/213, which:

1. Establishes new migration limits for Bisphenol A, will not exceed a specific migration limit of 0.05 mg of BPA per Kg of feed.
2. The use and migration of Bisphenol A in containers and packaging for infant foods, in the sense of EU 609/2013, is prohibited.
3. It is very clear that paints, varnishes and food contact coatings fall within the category of plastics of the EU Framework Regulation 10/2011, and that therefore they must comply not only with the EU regulation 2018/213 in relation to BPA, but also with all the requirements of the regulation of plastics EU 10/2011.
4. Reiterates that paints and varnishes for food contact must inexcusably have the mandatory detailed Compliance Declaration, which will be available in all stages of manufacturing, processing and distribution.

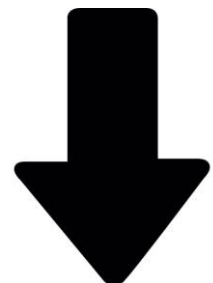
Therefore, users must be aware that paints and varnishes suitable for food contact must comply with extensive regulations that continually change, and to which FAKOLITH devotes important resources of Reserach and Quality Control, to ensure present and future hygiene and food safety for our clients, and their customers.

On the next page we indicate a checklist of the aspects to be met by manufacturers and their manufactured plastics, varnishes and paints for direct contact with food and beverages.

FAKOLITH CHEMICAL SYSTEMS  
(September 2018)  
[www.foodgradepaint.com](http://www.foodgradepaint.com)



**A CONTINUACIÓN Información adicional**



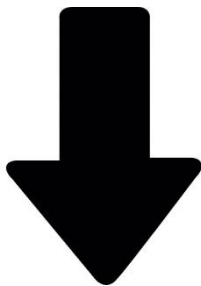
**BELLOW, Additional Information**

## FAKOLITH complementary information

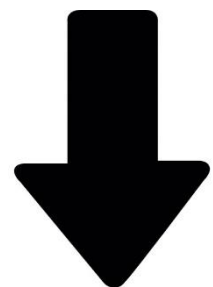
All paints and varnishes suitable for direct and indirect contact with foods and beverages (including those that may occasionally be, such as condensation drops from ceilings and other surfaces) must comply with extensive legislation that affects the manufacturer and the product. European (EU) and American (FDA) legislation are very strict, extensive and complex, so it is necessary to verify the compulsory Declaration of Compliance.

In order to verify, either by the Sanitary Inspection and the consumer, that a manufacturer and its products (in our case paints and varnishes suitable for direct and indirect contact with food and drinks) complies with all legal food and health safety requirements, the manufacturer is obliged to issue the **DECLARATION OF COMPLIANCE** of each commercialized product. In Paint's world it is erroneously known as "paint with food certificate" and in any case it is not just a test with a lot of sheets that nobody understand, but it is a manufacturer affidavit mandatory with date and legal signature in a format defined in EU 10/2011 and FDA 21 CFR 175.300, checked by Sanitary Authority and which must include :

- The RGSEAA EU Sanitary Register with code 39 of the manufacturer, where all manufacturers of materials and objects in contact with food and beverages must be registered without exception. It is easy to check this point thanks to the RGSEAA searcher web of the Spanish Food Consumption and Nutrition Agency (AECOSAN).
- As a sign of transparency, the last sanitary inspection date must be included to demonstrate with certainty that the manufacturer is up-to-date, or was simply registered in the past, but does not have the current validation of the Sanitary Inspection. Registration does not change, norms are updated constantly.
- No less important is the obligatory manufacture with good praxis (GMP) in accordance to Regulation EC 2023/2006 and FDA, which implies that the manufacturer has adapted its manufacture to the food sector, and therefore; an HACCP is applied, its staff is trained in food-sanitary security, production is done in a clean room apart from the rest of products, under microbiological and pest control, etc. It means that the producer applies analogous safety rules, storage, control and traceability as the food producer.
- To sum up, all the eligible external tests (global & specific migrations, organoleptic, chemical physical and CE mark) must be detailed including date and test number. These tests are usually inspected by Sanitary Authority and should always be available to users who request for its verification.



**A CONTINUACIÓN un CHECKLIST VISUAL  
BELLOW, VISUAL CHECKLIST**





**CERTIFIED**

**CERTIFIED**

**CERTIFIED**

**CHECK**

**STOP**

### Declaration of Compliance

- ✓ EU Manufacturer's Sanitary Register RGSEAA code 39
- ✓ Manufacture according GMP (Good Manufacturing Practices) CE 2023/2006 - HACPP - 21 CFR 170.39
  - Framework Regulation for direct contact CE 1935/2004
  - EU Plastics Regulation EU 10/2011 and UE 2018/213
  - For America FDA 21 CFR 175.300
    - + Its yearly amendments with new restrictions
  - Formulation according EU & FDA positive lists.
  - If epoxy, in addition CE 1895/2005
  - Suitability for cleaning and disinfection CE 852/2004
- ✓ Global migrations and extractions tests that will determine for which food groups and in which conditions will have aptitude for direct contact:
  - EU Food Simulants ( A, B, C, D, D2, E... ) at temperature conditions (from OM1 to Om7)
  - FDA - Water, heptane, and ethanol extractions according food type (I-VIII) and final use conditions (A-H)
- ✓ EU specific migrations tests according product type
  - Primary amines and heavy metals (all)
  - Badge, Bisfenol A, Epiclorhydrin, Formaldehyde, Phenols, etc. (depending on paint-varnish type)
- ✓ Organoleptic tests (to avoid smell and taste variations)
- ✓ Others: CE marking tests, Declaration of Performance, physical-chemical resistance tests, classification for clean rooms DIN EN ISO 14644-1 or VDI 2083.

Manufacturer's data, date and legal signature.

**FAKOLITH CHEMICAL SYSTEMS - SEPTEMBER 2018**