

Customer Communication

Siegwerk Printing Inks for Food Packaging — Regulations in Mercosur

Siegwerk receives inquiries about the suitability of its printing inks for food applications. The purpose of this statement letter is to clarify many of the issues that arise, including those concerning the regulatory bodies in Mercosur.

BACKGROUND

Mercosur or Mercosul (Spanish: Mercado Común del Sur, Portuguese: Mercado Comum do Sul) is an economic and political agreement among the founding States Parties Argentina, Brazil, Paraguay and Uruguay. Nowadays Venezuela is suspended and Bolivia in the process of accession.

Expert committees from the Mercosur countries are working on proposals and updates for regulations on food contact materials, the so called GMC Resolutions ("Grupo Mercado Común"). The regulations have been created on the basis of the current EU and U.S. regulations. All GMC Resolutions must be incorporated into national legislations in order to become effective. In Brazil, the Agência Nacional de Vigilância Sanitária (ANVISA) incorporates the GMC Resolutions into national Resolutions, in Argentina the Ministry of Health is responsible, in Uruguay it is the Ministry of Public Health and in Paraguay the Ministry of Public Health and Social Welfare¹.

The basic document is GMC Framework **Resolution N° 03/92** (Brazil: RDC N° 91, de 11 de maio de 2001) which provides general criteria for all food contact materials. It is thus required that all substances used in packaging and packaging materials intended to come into contact with foodstuffs must fulfill the positive list principle, that means, they must be included in one of the positive lists, and must comply with given migration limits.

General criteria for plastic packaging and articles are defined in the Mercosur GMC **Resolution N° 56/92** (Brazil: Resolução n° 105, de 19 de maio de 1999). Plastic materials covered are those that are

- a) consisting of one layer which is exclusively made of plastics
- b) consisting of two or more layers which are made exclusively of plastics or
- c) consisting of two or more layers, when one or more are not exclusively made of plastics, given that the layer in direct food contact is exclusively made of plastics (another one may be, for example, a layer of printing ink)

Every layer made of plastic must meet Mercosur resolutions for plastic packaging and articles regarding the positive list principle and migration limits.

All plastic materials that fall under the scope of the Mercosur Resolution N° 56/92 (as amended lastly by GMC **Resolution N° 20/21**) must be manufactured exclusively with substances that are included in the positive lists of compounds (resins, polymers, additives, etc.).

¹ In the following text, for all Mercosur Regulations, the respective ANVISA regulations in Brazil are mentioned.



The Overall Migration Limit of 60 mg residue/kg food simulant (or 10 mg residue/dm² of plastic surface area) and the Specific Migration Limits (SMLs) must be met.

INKS FOR DIRECT FOOD CONTACT

There is no regulation in place in the Mercosur states that specifically addresses printing inks. Nevertheless, coatings made of plastics that are intended to come into direct contact with food would fall under the scope of the GMC Resolution N° 56/92 and would have to be produced with using only substances of the positive lists. Additionally, pigments and colorants used for coloration of food contact packaging and articles made of plastics are required to comply with the specific technical Mercosur regulations.

INKS FOR NON-DIRECT FOOD CONTACT

In the Mercosur states, there is no specific regulation for printing inks intended for non-direct food contact. Nevertheless, an outside-printed food packaging material, if it is a plastics material, which falls under the scope of the GMC Resolution N° 56/92, must meet the overall and specific migration limits when it is tested for compliance. As the printing ink becomes part of the plastic packaging, the migration of substances that are both part of the plastic packaging and at the same time also used in the printing ink must be considered with their combined effects.

According to general criteria in GMC **Resolution N° 39/19** (RDC N° 326, de 3 de dezembro de 2019) plastic materials and coatings either colored or printed shall not release primary aromatic amines, excluding those appearing in the same resolution, in a detectable quantity into food or food simulant. The detection limit is 0.01 mg of substance per kg of food or food simulant. The detection limit applies to the sum of primary aromatic amines released.

In this respect, printing inks for non-direct food contact are indirectly covered by the Mercosur legislation and must not contain potential migrants in an amount that would possibly lead to an exceedance of the given migration limits.

SUMMARY

Siegwerk's inks and varnishes that are clearly identified for NPH (Nutrition, Pharma & Hygiene) packaging applications use are primarily designed and considered safe for non-direct food contact applications, meaning that an effective functional barrier to migration exists. They are formulated in such a way as to minimize potential migration of concern both through the substrate and by set-off from the printed outer side to the food contact surface. This means, the formula is designed in a way that the final packaging as produced under the control of the printer/converter can meet the relevant thresholds. Furthermore, even though it is not explicitly required for printing inks, but rather for mass colorants, Siegwirk uses only such colorants in inks, which comply with the criteria of the GMC Resolution N° 56/92.

If a Siegwirk ink system will be utilized in such a manner that it may reasonably be expected to come into direct contact with the food, Siegwirk inks would then fall under the regulations and would require compliance with the positive lists. In these cases, please contact your Siegwirk Sales or Technical Account Manager and discuss the requirements for your application.

The information in this document reflects Siegwirk's policy and commitments. This statement is valid without signature.