

MERCOSUR/GMC/RES. No. 15/10

**MERCOSUR TECHNICAL REGULATION ON COLORANTS IN FOOD-CONTACT
PLASTIC PACKAGING AND EQUIPMENT**

(REPEAL OF GMC RES. No. 28/93)

HAVING REGARD TO: The Treaty of Asunción, the Protocol of Ouro Preto, and Resolution Nos. 28/93, 38/98, 56/02 and 32/07 of the Common Market Group (GMC).

WHEREAS:

The harmonization of Technical Regulations tends to eliminate the obstacles to trade generated by the various national regulations in force, pursuant to the provisions in the Treaty of Asunción.

The State Parties, owing to the advances on the subject, considered it necessary to update the Technical Regulation on food-contact plastic packaging and equipment.

It is necessary to adapt the methodology for verifying compliance with the requirements established by GMC Resolution No. 32/07 for carbon black colorant.

It is appropriate to establish specific migration limits for heavy metals in food-contact plastic packaging and equipment.

It is necessary to establish requirements for the content of sulfonated aromatic amines and benzidine, beta-naphthylamine, and 4-aminobiphenyl.

**THE COMMON MARKET GROUP
RESOLVES:**

Art. 1. To approve the “MERCOSUR Technical Regulations on Colorants in Food-Contact Plastic Packaging and Equipment,” which is included as an Appendix and is part of this Resolution.

Art. 2. The national entities capable of implementing this Resolution are:

Argentina: Ministry of Health
Secretariat of Policies, Regulation, and Institutes
Ministry of Agriculture, Livestock, and Fisheries
Secretariat of Agriculture, Livestock, and Fisheries

Brazil: National Health Surveillance Agency (ANVISA)
Ministry of Health (MS)

Paraguay: Ministry of Industry and Commerce (MIC)
National Institute of Technology, Normalization and Metrology (INTN)
Ministry of Public Health and Social Welfare (MSPyBS)
National Institute for Food and Nutrition (INAN)

Uruguay: Ministry of Public Health (MSP)
Ministry Industry, Energy and Mining (MIEM)
Technological Laboratory of Uruguay (LATU)

Art. 3. This Resolution shall be applied in the territory of the State Parties, to the trade among them, and to the imports from outside the zone.

Art. 4. Repeal GMC Resolution No. 28/93.

Art. 5. This Resolution must be included in the State Parties' legal systems by December 15, 2010.

LXXX GMC - Buenos Aires, June 15, 2010.

[signatures]

APPENDIX

MERCOSUR TECHNICAL REGULATION ON COLORANTS IN FOOD-CONTACT PLASTIC PACKAGING AND EQUIPMENT

1. Scope

This Technical Regulation shall apply to plastic packaging and equipment containing colorants in their formulation intended to come into contact with foods, as well as to the colorants used for the coloration of plastic packaging and equipment, establishing the requirements with which these, and the analytical methods involved in their control, must comply.

The specific migration requirements for metals and other elements established in item 3.2. of this Technical Regulation shall also apply to printed plastic packaging and equipment, unless there is a barrier that keeps the ink from contacting the internal surface of the material.

For the purposes of this Regulation, colorants are understood to be the colored substances that include the colorants themselves and the organic and inorganic pigments used as additives that are added to plastic materials.

2. Requirements for colorants

Verification of compliance with the requirements of this Regulation will be performed on colorants in the form of active ingredients and not on the colorants included in a polymer ("masterbatch").

2.1 Requirements for unsulfonated aromatic amines in organic colorants

The content of primary unsulfonated aromatic amines soluble in 1 M hydrochloric acid, expressed as aniline, must not exceed 500 ppm (mg/kg) of the colorant mass (0.05% m/m).

The content of benzidine, β -naphthylamine and 4-aminobiphenyl, alone or combined, must not exceed 10 ppm (mg/kg).

Analytical methods:

Standard DIN 55 610 (1986) "Determination of unsulfonated primary aromatic amines" shall be used to determine the content of unsulfonated aromatic amines.

Sufficiently sensitive quantification methods must be used to verify compliance with the limits established for benzidine, β -naphthylamine and 4-aminobiphenyl.

2.2 Requirements for sulfonated aromatic amines in organic colorants

The total content of sulfonated aromatic amines expressed as aniline sulfonic acid must not exceed 500 ppm (mg/kg) of the colorant mass (0.05% m/m).

Analytical methods:

Resolution AP(89)1 on the use of colourants in plastic materials coming into contact with food, of the Council of Europe, Committee of Ministers, 1989, Section III, Paragraph 4.

2.3. Requirements on metals and metalloids in colorants

From the date this Technical Regulation enters into force, colorants shall not contain metals or metalloids in quantities exceeding the following percentages:

Antimony	(Sb)	(soluble in HCl 0.1 N)-----	0.05	% m/m
Arsenic	(As)	(soluble in HCl 0.1 N)-----	0.005	% m/m
Barium	(Ba)	(soluble in HCl 0.1 N)-----	0.01	% m/m
Cadmium	(Cd)	(soluble in HCl 0.1 N)-----	0.01	% m/m
Zinc	(Zn)	(soluble in HCl 0.1 N)-----	0.20	% m/m
Chromium	(Cr)	(soluble in HCl 0.1 N)-----	0.10	% m/m
Mercury	(Hg)	(soluble in HCl 0.1 N)-----	0.005	% m/m
Lead	(Pb)	(soluble in HCl 0.1 N)-----	0.01	% m/m
Selenium	(Se)	(soluble in HCl 0.1 N)-----	0.01	% m/m

Analytical methods:

a) Methods for extracting metals and metalloids

Resolution AP(89)1 on the use of colourants in plastic materials coming into contact with food, of the Council of Europe, Committee of Ministers, 1989, Section III, Paragraph 2.

Standard DIN 53770-1 on Pigments and Extenders - Determination of Matter Soluble in Hydrochloric Acid, 2007, Part 1, item 3 - Apparatus shall be used for filtration procedures.

b) Methods for quantifying metals and metalloids

Metal and metalloid content in the extracts shall be determined by spectrometric techniques of quantification sensitive enough to verify compliance with the established limits.

2.4. Requirements and additional testing for carbon black pigment

Carbon black pigment must meet the following specifications:

- Extractable in toluene: maximum 0.1% m/m
- Extractable in cyclohexane at 386 nm <0.02 AU for a 1 cm cell or <0.01 AU for a 5 cm cell. Absorption of the clear extract in ultraviolet light (386 nm wavelength) is determined by 1 g of the sample in contact with 100 ml of cyclohexane for 24 hours in darkness and filtration.
- Benzo(a)pyrene content: maximum 0.25 mg/kg (ppm) m/m
- Carbon black in polymer: maximum 2.5% m/m

Analytical methods:

- For pigments extractable in toluene: Standard ISO 6209-1988.
- For pigments extractable in cyclohexane: German BfR, BIII, Reinheitsprüfung von Rußen, Stand 1.7.1972.

Quantification methods with enough sensitivity to verify compliance with the established limits will be used for the rest of the determinations.

3. Testing for food-contact printed plastic packaging and equipment and/or plastic packaging and equipment that contain colorants in their formulation

3.1. Determining migration of substances that transfer color

Overall migration testing of plastic packaging and equipment that contain colorants in their formulation is conducted with simulants at the temperatures and contact times listed in the GMC Resolutions corresponding to the allowance of food simulants and to overall migration testing. The extracts obtained in the overall migration testing are visually compared with the respective blanks against a white background.

In these conditions, there should be no visibly appreciable differences between the coloring of the extract and its blank.

3.2. Determining specific migration of metals and other elements

The concentrations of metals and other elements in the collected extracts are determined as described in the section on overall migration testing of plastic packages and equipment in the corresponding GMC Resolutions. If applicable, determining specific migration of metals and other elements shall only be performed in an acidic aqueous simulant (3% acetic acid m/v in distilled water), even if the food to be packaged does not have an acidic aqueous constitution.

Spectrometric techniques with the greatest selectivity and sensitivity available are used on the extracts to determine the metals and other elements.

The specific migration limits (SMLs) of the elements to be determined are the following:

Element	SML in mg/kg
Antimony	0.04
Arsenic (As)	0.01
Barium (Ba)	1
Boron (B)	0.5
Cadmium (Cd)	0.005
Zinc (Zn)	25
Copper (Cu)	5
Chromium (Cr)	0.05
Tin (Sn)	1.2
Fluorine (F)	0.5
Mercury (Hg)	0.005
Silver (Ag)	0.05
Lead (Pb)	0.01

Metal and metalloid content in the extracts shall be determined using spectrometric techniques of quantification sensitive enough to verify compliance with the established limits.

The packaging must comply with the limits established in this Regulation.

When the packaging is intended for foods with established contaminant limits, the packaged foods must not exceed the values established for that particular food product.