

MERCOSUR/GMC/RES N° 56/98

MERCOSUR TECHNICAL REGULATION FOR FLUORINATED POLYETHYLENE FOR THE MANUFACTURING OF FOOD CONTACT PACKAGING AND EQUIPMENT

Seen: The Treaty of Assumption, the Protocol of Ouro Preto, Resolutions No. 56/92, 91/93, 152/96 and 38/98 of the Common Market Group and Recommendation No. 71/97 of SGT No. 3 "Technical Regulations".

Considering:

That fluorinated polyethylene containers and equipment intended to come into contact with food are the result of a new technological process that improves the shelf life of certain foods.

That it is desirable to have common regulations on such packaging and equipment.

THE COMMON MARKET GROUP RESOLVES:

Article. 1: Fluorinated polyethylene containers and equipment intended to come into contact with food shall be manufactured in accordance with the provisions of the Technical Regulations "Technical Regulation for Fluorinated Polyethylene for the manufacturing of Packaging and Equipment in Contact with Food", in its Spanish and Portuguese versions, which is annexed and is part of this Resolution.

Article. 2: The art. 1 shall not apply necessarily to food packaging intended for export to third countries.

Article. 3: States Parties shall implement the legislative, regulatory and administrative provisions necessary for the implementation of this Resolution through the following bodies:

Argentina:

1. Ministry of Economy and Public Works and Services
 - 1.1 Ministry of Agriculture, Livestock, Fisheries and Food
 - 1.1.1 National Service for Health and Agro-Food Quality.
 - 1.1.2 National Institute of Viticulture (INV).
2. Ministry of Health and Social Action
 - 2.1. National Administration of Medicines, Food and Medical Technology.

Brazil:

1. Ministry of Health

Paraguay:

1. Ministry of Industry and Trade
 - 1.1. National Institute of Technology and Standardization (INTN)
2. Ministry of Public Health and Social Welfare
 - 2.1. National Institute of Food and Nutrition (INAN).

Uruguay:

1. Ministry of Public Health (MSP).

Article. 4 This Technical Regulation shall apply in the territory of the States Parties, to trade between them and to imports from place.

Article. 5 States Parties to MERCOSUR shall incorporate this Resolution into their domestic legal systems by 7/VI/99.

XXXII GMC - Rio de Janeiro, 16/IX/98

TECHNICAL REGULATION FOR FLUORINATED POLYETHYLENE FOR THE MANUFACTURING OF FOOD CONTACT PACKAGING AND EQUIPMENT

1. Scope

This document applies to fluorinated polyethylene packaging and equipment, intended to come into contact with food or food raw materials, and to containers composed of various types of materials provided that the face in contact with the food is of fluorinated polyethylene.

2. Definition

Fluorinated polyethylene containers and equipment are those made from polyethylene objects or their authorized copolymers, modified on their surface by fluoride gas treatment in combination with nitrogen gas as an inert diluent. Such modification affects only the surface of the polymer, leaving its interior unchanged.

3. The packaging and equipment of fluorinated polyethylene referred to in this regulation shall be manufactured in accordance with good manufacturing practices, compatible with their use for direct contact with food.

Ethylene copolymers	Density (g/cm ³)	Content of polymer units derived from ethylene	Restrictions on use
1-octene	0,85 - 1,00	Minimum 90 %	(I)
1-octene	0,9 - 1,00	Between 85 and 90 %	(II)
1-hexene	0,85 - 1,00	Minimum 85 %	(I)
1-pentene	Minimum 0.92	Minimum 90 %	(III)
Isobutene (4-methyl-1-pentene)	0,85 - 1,00	Minimum 89 %	(I)
Propylene and/or 1-butene and/or isobutene	0,85 - 1,00	Minimum 85 %	(I)
1-hexene and propylene	0,85 - 1,00	Minimum 85 %	(I)
Ethylene copolymers	Density (g/cm ³)	Content of polymer units derived from ethylene	Restrictions on use
1-hexene and 1-butene	0,85 - 1,00	Minimum 85 %	(I)
1-octene and 1-hexene	0,9 - 1,00	Minimum 85 %	(II)

1-octene and 1-butene	0,9 - 1,00	Minimum 85 %	(II)
1-octene and propylene	0,9 - 1,00	Minimum 85 %	(II)
1-octene and isobutene	0,9 - 1,00	Minimum 85 %	(II)

(I) not for cooking.

(II) for fatty foods not at temperatures above 65°C.

(III) not at temperatures above 65°C.

4. For the manufacture of the objects to be then subjected to fluoride treatment, only:

4.1. The polymers or copolymers mentioned below:

4.1.1. Polyethylene, density 0.85 to 1.00 g/cm³, complying with the restrictions of use of (I).

4.1.2. Ethylene copolymers, obtained by catalytic copolymerization of ethylene with the monomers listed in the table and complying with the corresponding specifications:

4.2. The substances or groups of substances included in the positive lists of additives of Res./GMC No. 95/94, complying with the restrictions set in each case.

5. Fluorinated polyethylene packaging and equipment in contact with food shall comply with the regulations laid down in GMC Resolutions. 30/92, 36/92, 56/92, 28/93, 87/93 and 95/94 and, furthermore, no more than 5 mg/kg of fluoride ion shall be transferred to food, thus establishing, in this case, an LME = 5mg/kg fluoride ion.

The specific migration of fluoride ion will be evaluated by the analytical methodology of the corresponding MERCOSUR regulation.

6. The manufacturing process and the packaging and equipment of fluorinated polyethylene intended to come into contact with food must be previously authorized/approved by the Competent Health Authority.

7. Users of fluorinated polyethylene packaging and equipment intended to come into contact with food may only use those authorized/approved by the Competent Health Authority.

8. All modifications to the composition of fluorinated polyethylene packaging and equipment intended to come into contact with food must be communicated to the Competent Authority for authorization/approval.

9. This regulation may be amended:

- For the inclusion of new materials, where it is shown that they do not pose a significant risk to human health and the technological need for their use is justified.
- For the exclusion of materials, in case new technical-scientific knowledge indicates a significant risk to human health.
- For modification of restrictions (specific migration limits, composition limits, usage restrictions), in case new technical-scientific knowledge warrants it.

Proposals for amendment shall be processed through the presentation of a precedent justified in a manner similar to that indicated in Resolution GMC No. 87/93.