

RUBBER

1. Scope

This section deals with materials and objects in rubber which, as finished products, are intended to be in contact with food products.

Rubber means a natural or synthetic polymer with a high elastic stretch rate made up of carbonaceous macromolecules generally obtained by cure. Thermoplastic elastomers, which do not require cure, are included in rubbers.

The main application examples are the following elements:

- Pressure cooker, jar and stopper seals;
- Pipes;
- Conveyor belts;
- Gloves;
- Gate parts;
- Dummies and teats.¹

The materials and objects in silicon elastomers and joints for cans are not included.

2. Restrictions of use for materials

- Restrictions of use may exist for materials which contain some additives. All useful information shall be communicated to the laboratories.

3. Definitions of performance criteria for food contact

3.1 Texts to be used

3.1.1 Regulatory texts

Order of 9 November 1994 relating to materials and objects in rubber intended to be in contact with foodstuffs.

3.1.2 Other texts

Order of 2 January 2003 relating to materials and objects in rubber intended to be in contact with foodstuffs.

Order of 25 November 1992 relating to materials and objects silicon elastomers intended to be in contact with foodstuffs.

Other texts (circulars, circular letters, instructions etc) put together in Brochure No. 1227 of the Official Journal of the French Government.

3.2 Criteria to be used

¹ Rubber dummies, although they are not in contact with foods, are mentioned in the order of 9 November 1994 relating to materials and objects in rubber in contact with foodstuffs. Furthermore, the approval procedure for teats and dummies other than those in pure hot cured rubber has been removed by decree No.97-503 of 21 May 1997 which simplifies administrative measures.

At each manufacturing stage of a material or an object, the producer shall ensure that the various constituents used are mentioned in the positive lists.

When the product or the material is finished, the manufacturer or user shall check that the inertia criteria are met, i.e.:

- Compliance with the positive list (monomers and additives ²) and limitations of use in compliance with the order of 09/11/1994, evidence of conformity from supplier
- Overall migration according to the order of 09/11/1994.
- Specific migration of monomers and/or residual quantity of monomers in the material or object in accordance with the order of 09/11/1994 ³;
- Specific migration of additives ³ or quantity of additives in the material or object in accordance with the order of 09/11/1994;
- Volatile organic materials;
- Migration of N-nitrosamines and N-nitrosatable substances;
- Migration of aromatic amines;
- Migration of formaldehyde;
- Peroxides.

4. Acceptability limits

Criterion	Limit
Overall migration	10 mg/dm ² or 60 mg/kg according to the shape and capacity of the object <i>(analytic tolerance: cf. chapter VI of the annex to the order of 2 January 2003)</i>
Specific migration of monomers and additives	See. limits laid down in the order of 09/11/1994
Volatile organic materials	0.5 %
Migration of N-nitrosamines and N-nitrosatable substances	All articles except dummies and teats: Ni-nitrosamines: 1 µg/dm ² . N-nitrosatable substances: 10 µg/dm ² . Teats and dummies: Ni-nitrosamines: 10 µg/kg ⁴ . N-nitrosatable substances: 100 µg/kg ⁴ .
Migration of aromatic amines	1 mg/kg.
Migration of formaldehyde	3 mg/kg.
Peroxides.	Absence of positive reaction to peroxides according to the French pharmacopoeia, Xth edition.

² For additives, reference may be made to the positive list provided for plastic materials while waiting for the amendment of the order of 09/11/1994.

³ Checking specific migration limits is not obligatory if it can be established that the result of the overall migration test implies that the specific migration limits have not been exceeded, or that the specific migration limit cannot be exceeded even if all the residual substance migrated.

Respect of the specific migration limits can be checked by determining the quantity of the substance in the material, provided that a relationship between this quantity and the value of the specific migration of the substance has been established either by a suitable experiment, or by the application of generally recognised diffusion models (order dated 2 January 2003, article 8).

⁴ Limits expressed according to the rubber quantity

5. Rules to check the criteria defined in paragraph 3.

- To check the performance criteria to contact with food, the following information must be supplied to the laboratory:

- Nature of monomers and additives subject to specific migration limits or maximum residual quantities.
- Contact conditions (duration and temperature);
- Type of food in contact or simulator liquids.

Criteria	Test conditions	Test methods
Overall migration	According to the category the object belongs to (A, B, C, D, T) see. annex III of the order of 09/11/1994	see order of 02/01/2003 and directives 82/711 amended and 85/572 + Overall migration: standards NF XP ENV 1186.
Specific migration		
Aromatic amines ⁵		
Formaldehyde ⁶		
N-nitrosamines and N-nitrosatable substances;		Articles other than dummies and teats: see method in the annex Teats and dummies: see appendix IV of the order of 09/11/1994
Volatile organic materials	4 hours at 105°C see order of 25/11/1992, annex III, section 2	
Peroxides.	French pharmacopoeia, Xth edition	

⁵ For secondary aromatic amines, there is no valid method of analysis, but if these substances are present in the material they will be detected as nitrosatable substances.

⁶ Primary aromatic amines and formaldehyde cannot be detected in the fat simulator, but the acid simulator, being the more extractive medium, the aqueous simulators are sufficient