

COUNCIL OF EUROPE
COMMITTEE OF MINISTERSResolution ResAP(2004)5
on silicones used for food contact applications

(Adopted by the Committee of Ministers on 1 December 2004
at the 907th meeting of the Ministers' Deputies)
(replacing Resolution AP (99) 3)

The Committee of Ministers, in its composition restricted to the Representatives of the States members of the Partial Agreement in the Social and Public Health Field,¹

Recalling Resolution No. R (59) 23 of 16 November 1959 concerning the extension of the activities of the Council of Europe in the social and cultural fields;

Having regard to Resolution No. R (96) 35 of 2 October 1996, whereby it revised the structures of the Partial Agreement and resolved to continue, on the basis of revised rules replacing those set out in Resolution No. R (59) 23, the activities hitherto carried out and developed by virtue of that resolution; these being aimed in particular at:

a. raising the level of health protection of consumers in its widest application: including onstant contribution to harmonising – in the field of products having a direct or indirect impact on the human food chain as well as in the field of pesticides, pharmaceuticals and cosmetics – legislation, regulations and practices governing, on the one hand, quality, efficiency and safety controls for products and, on the other hand, the safe use of toxic or noxious products;

b. integrating people with disabilities into the community: defining – and contributing to its implementation at European level – a model coherent policy for people with disabilities, which takes account simultaneously of the principles of full citizenship and independent living; contributing to the elimination of barriers to integration, whatever their nature, whether psychological, educational, family-related, cultural, social, professional, financial or architectural;

Having regard to the action carried out for several years for the purposes of harmonising legislation in the public health field and, in particular, with regard to materials and articles intended to come into contact with foodstuffs;

Considering that silicones used for food contact applications may, by reason of the migration of their components to the foodstuffs, pose a risk to human health;

Taking the view that each member state, faced with the need to introduce regulations governing this matter, would find it beneficial to harmonise such regulations at European level,

Recommends to the governments of the States members of the Partial Agreement in the Social and Public Health Field to take into account in their national laws and regulations on silicones used for food contact applications the principles set out hereafter.

Appendix to Resolution ResAP(2004)5
on silicones used for food contact applications

1. Definition

Silicones constitute a group of polymeric chemical substances and preparations, all containing polysiloxanes. Polysiloxanes are characterised by Si-O-Si and Si-C bonds. They are prepared from chlorosilanes which are subjected to hydrolysis. Polysiloxanes such as fillers, emulsifiers and are also covered by the definition. Furthermore, copolymers or polymer-blends of polysiloxanes with organic polymers are covered by the term "silicones", provided siloxane monomer units predominate by weight over each of the other monomer units present. Silicones used as food additives are not covered by the definition.

2. Description of the silicone product group

Silicones include a range of products with a variety of properties and applications:

2.1. silicone elastomers: coatings, sealants, etc.;

2.2. silicone liquids: additives to plastics and coatings, release agents for moulding plastic articles, impregnating agents for textiles, etc.;

2.3. silicone pastes: lubricants for food processing machinery etc.;

2.4. silicone resins: heat-resistant coatings, release coatings in food production such as bakery, etc.

3. Specifications

Silicones used for food contact applications, hereafter called silicones, should meet the following requirements:

3.1. they should not transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or deterioration in the organoleptic characteristics thereof;

3.2. they should be manufactured in accordance with a certified Quality Assurance System (for example, ISO 9002 or CEN 29-004) and under the conditions specified in "Technical document No. 1 – List of substances used in the manufacture of silicones used for food contact applications";

3.3. interactions between starting substances or between starting substances and any other substance used in the manufacturing process of silicones should not lead to the formation of compounds which pose a risk to human health;

3.4. linear siloxanes containing methyl- and phenyl- groups attached to the same silicone atom and also containing two methyl- groups attached to one silicon atom (siloxanes and silicones, Me-, Ph-, di-Me-) should not be used as starting substances, in order to prevent the formation of certain phenyl-substituted cyclic polydimethylsiloxanes;

3.5. the release of any substance from silicones to foodstuffs should be as low as technologically possible. The total of all substances migrating into food from silicone materials or articles should not exceed 10 mg/dm² of the surface area of the final material or article or 60mg/kg of food, this being considered as the overall migration limit;

3.6. the migration limits set out in "Technical document No. 1 – List of substances used in the manufacture of silicones used for food contact applications" should be met;

3.7. migration tests should be conducted according to Directives 82/711/EEC, 85/572/EEC, 90/128/EEC, 93/8/EEC, 97/48/EEC and their future amendments, as appropriate, unless technically impracticable due to the nature of the material and the migration tests;

3.8. appropriate labelling for the materials or articles should be provided, if pre-washing by the user is necessary.