

Rubber as a food contact material

Currently, there is no EU legislation specifically for rubber as a food contact material. Rubber must comply with the requirements of the framework regulation 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and regulation 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food. In the absence of EU legislation, some member states have adopted their own legislation on rubber as a food contact material.

This statement covers rubbers of the following types with the designation "FDA":

- SBR
- IIR
- HNBR
- NBR
- EPDM
- FPM (FKM)
- VMQ
- FFKM
- Kalrez

Regulation 1935/2004

According to Article 3, materials in contact with food should not transfer their constituents to food in quantities which could:

- (a) endanger human health
- (b) bring about an unacceptable change in the composition of the food
- (c) bring about a deterioration in the organoleptic characteristics thereof.

How compliance with Article 3 is demonstrated, is not specified in Regulation 1935/2004. The Council of Europe has issued a Policy Statement which describes how to demonstrate compliance with Article 3.

Council of Europe Resolution ResAP (2004) 4 on Rubber products intended to come into contact with foodstuffs

The resolution refers to a list of substances (Technical Document No. 1) to be used in the manufacture of rubber products. However, this list has never been published. Appendix 1 contains an inventory list of substances used for the manufacture of rubber products. However, being 20+ years old, the list is outdated.

Rubber products are classified in three categories:

I: feeding teats and products in contact with baby food for which $R_{\text{total}} \geq 0.001$.

II: rubber products for which $R_{\text{total}} \geq 0.001$

III: rubber products for which $R_{\text{total}} < 0.001$

R_{total} is the product of four factors describing contact time, temperature, surface area, and number of recurrent uses.

GMP

All rubber articles sold as food contact materials are manufactured according to Good Manufacturing Practice in accordance with Regulation 2023/2006.

FDA

All rubber articles, except for FFKM and Klarez, sold as food contact materials are in compliance with 21 CFR § 177.2600 Rubber articles intended for repeated use and have been tested for migration in water and hexane. FFKM and Kalrez have been notified as food contact substances in accordance with 21 CFR § 174.5(d)(5).

Risk Assessment

The overall migration limit according to 21 CFR § 177.2600 is 175 mg/inch² corresponding to 2713 mg/dm² when extracted with hexane for 7 hours. The amount of hexane to use when testing is not specified but is low compared to the amount of food expected to come into contact with the rubber, the contact time is high, and the surface area is very high. That is, the migration limits ensure that migration to food is low under realistic conditions of use, i.e., short contact time, small surface area, and large amount of food.

Calculations assuming worst-case, i.e., all of the constituents of the sealing migrate to the food (which is not realistic), show that migration is negligible. Section 8 of Technical Document No. 2 in the Council of Europe Resolution have calculations showing that migration is indeed very low when rubber is used as a sealing.

M Seals' Position

Considering that sealings are only in contact with the food for a short time, the surface area is small, and the amount of food in contact with the sealing is large, R_{total} is below 0.001 which means that migration testing is not required according to the Council of Europe Resolution.

The very low migration under reasonably foreseeable conditions of use means that all three points of Article 3 of Regulation 1935/2004 can be considered fulfilled.

It is the customer's responsibility to make sure that the conditions for negligible migration, i.e., large amount of food in contact with the sealing, is met to ensure compliance with Regulation 1935/2004. Sections 7 and 8 of Technical Document No. 2 in the Council of Europe Resolution provide examples showing when the conditions are met.

Rubber articles intended for repeated use in contact with food should always be thoroughly cleansed prior to their first use in contact with food.