

EU & FDA Regulatory Compliance Statement for gloves intended to come into contact with food

Product: Showa 6110PF (all sizes)

Intended Food Contact Conditions: Gloves for handling all food types

We confirm that the above mentioned product is in conformity with the applicable requirements of the following regulations and standards:

- Regulation (EC) no.1935/2004 on Materials and Articles intended to come into contact with food including Article 3 (General requirements) and Article 17 (Traceability)
- Regulation (EC) no. 2023/2006 on Good Manufacturing Practice for materials and articles intended to come into contact with food.
- Council of Europe Resolution AP (2004)4) on rubber products intended to come into contact with foodstuffs.
- Compositional and extraction requirements (distilled water and n-hexane) of FDA 21 CFR 177.2600 Rubber articles intended for repeated use
- BfR Recommendation XXI -Commodities based on Natural and Synthetic Rubber
- French regulatory requirements for food contact rubber - (Arrêté du 9 Novembre 1994 relatif aux matériaux et objets en caoutchouc au contact des denrées produits en boissons alimentaires).
- Italian Ministerial Decree of 21 March 1973, (Disciplina igienica degli imballaggi, recipienti, utensili, destinati a venire in contatto con le sostanze alimentari o con sostanze d'uso personale. G.U. n. 104 del 20 aprile 1973 as amended.)
- Spanish Royal Decree 847/2011

When used as intended, the overall migration and specific migration of substances subject to restriction do not exceed the legal limits (calculated as 6 dm² glove per 1kg of food).

This compliance statement is based on information received from material suppliers, migration testing undertaken according to Directive 82/711/EEC, 85/572/EEC and EU Regulation 10/2011 and quality control systems in place at Showa Glove. Supporting documents are available and can be disclosed to the competent authority on request.

Test Simulants	Food Types	Testing Condition
A, B, C, D1, D2 of Regulation No.10,2011 for Plastic Materials and Articles in contact with food	All dry, aqueous and fatty foods	2 hours at 70°C, Repeat Use

No migratory dual use food additives subject to a quantitative or compositional restriction in food (Directives 2008/60/EC, 95/45/EC and 2008/84/EC) are associated with these gloves.

October 27, 2021



Elaine Turner

R&D Jr. Chemist/Technical Support