EU & FDA REGULATORY COMPLIANCE STATEMENT

FOR GLOVES INTENDED TO COME INTO CONTACT WITH FOOD

DECLARE THAT THE NEW PERSONAL PROTECTIVE EQUIPMENT DESCRIBED HEREAFTER:

SHOWA 7545 EBT

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SIMULANTS

A, B, C, D1, D2 of Regulation No.10,2011 for Plastic Materials and Articles in contact with food.

FOOD TYPES

All dry, aqueous, acidic, alcoholic and fatty foods.

TESTING CONDITIONS

2 hours at 70° C, repeat Use

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..
• French regulatory requirements for food contact rubber – (Order of the 5th August 2020)
• BfR Recommendation XXI (April 2022) – Commodities based on natural and synthetic rubber
• Italian Ministerial Decree of 21 March 1973,
• Netherlands regulatory requirements, Chapter III of the Dutch packaging and food utensils regulations (RVG) for rubber products in contact with food (Staatscourant No. 8531 of the 27/03/2014).
• 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.
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.

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Signed for and on behalf of SHOWA Glove Co.

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