

EU & FDA REGULATORY COMPLIANCE STATEMENT

FOR GLOVES INTENDED TO COME INTO CONTACT WITH FOOD

DECLARE THAT THE NEW PERSONAL PROTECTIVE EQUIPMENT DESCRIBED HEREAFTER:

SHOWA 6781R



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.
- Council of Europe Resolution AP (2004)4) on rubber products intended to come into contact with foodstuffs.
- 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.)
- 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 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.

Additional Information

All components of the black colorant have been confirmed by the manufacturer as meeting the purity requirements of EU Regulation 10/2011. The toluene extractable fraction of the carbon black also meets the requirements of the Council of Europe regulation AP89:1.

The dual use food additive E640 (Glycine) is associated with these gloves.

Neoprene rubber is not approved for food contact use in France due to the non-listing of its monomer chloroprene.



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SUS

Signed for and on behalf of SHOWA Best Glove Inc.

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