

## EU & FDA REGULATORY COMPLIANCE STATEMENT

### FOR GLOVES INTENDED TO COME INTO CONTACT WITH FOOD

#### DECLARE THAT THE NEW PERSONAL PROTECTIVE EQUIPMENT DESCRIBED HEREAFTER:

#### SHOWA NSK24



#### SIMULANTS

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

#### FOOD TYPES

All dry, aqueous and fatty foods

#### TESTING CONDITIONS

2 hours at 70° C, repeat use

is in conformity with the provisions of:

Regulation (EC) No 1935/2004: Materials and articles intended to come into contact with food.

Regulation (EC) No 2023/2006: Good Manufacturing Practice for Materials and Articles intended to come into contact with food.

Regulation AP (2004)4: Rubber products intended to come into contact with foodstuffs.

France – Arrêté du 9/11/1994 relatif aux matériaux et objets en caoutchouc au contact des denrées, produits en boissons alimentaires

Germany – BfR Recommendation XXI for rubber materials in contact with food

Netherlands – Chapter III of the Dutch packaging and food utensils regulations (RVG) for rubber products in contact with food (Staatscourant No.18 of the 25/01/1980 with applicable amendments through to No. 67 of 04/04/2003)

Italy – 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

Spain – 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 dm<sup>2</sup> glove per 1 kg of food).

This compliance statement is based on information received from material suppliers, migration testing undertaken according to Directive 82/711/EEC and 85/572/EEC, mathematical modelling and quality control systems in place at SHOWA. Supporting documents are available and can be disclosed to the competent authority on request. Although dual use food additives are present in these gloves, they are inorganic and none migratory.

This Declaration is for the product specified above and is valid for two years. An updated statement will be provided if the information on which the declaration is based changes or regulatory requirements impact on its validity.



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**BRIAN MOSELEY**  
RAQA Technical Manager  
SAO

Signed for and on behalf of SHOWA Best Glove Inc.

02/05/2024  
579Edison  
Street  
Menlo,GA  
30731USA

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