



EU DECLARATION OF COMPLIANCE FOOD DECLARATION

Rubberex Spain S.L.
Polígono Industrial Masía del Baló
C/Más Vallesa de Mandor nº8
Ribarroja del Turia 46190
Valencia. España

Glove
Nitrile Green 6.0 Rubberex



DECLARE

Declares according to the Regulation:

(EC) No 2023/2006: on good manufacturing practice for materials and articles intended to come into contact with food.

(EC) No 1935/2004: Declaration of compliance for materials and articles intended to come into contact with food.

The sample examined is under the standards:

UNE-EN 1186-3: 2022: Materials and articles in contact with foodstuffs. Plastics. Part 3: Test methods for overall migration into aqueous food simulants by article filling.

UNE-EN 1186-2:2022: Materials and articles in contact with foodstuffs. Plastics. Part 2: Test methods for overall migration into olive oil by article immersion.

The glove complies with the requirements:

Regulation (EU) No 10/2011: commission dated 14 January 2011.

The maximum limit global migration following the Regulation (EU) No 10/2011 commission dated 14 January 2011: 60 mg/kg or 10 mg/dm².

SIMULANTS	Food Type	TESTING CONDITIONS
B*, D1* Y D2*	All types of Food	30 minutes at a temperature of 40°

*Simulant A (ethanol 10%), B (acetic acid 3%), D1 (ethanol) 50% and D2 (vegetable oil).

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VALENCIA, ESPAÑA, 46190

Teléfono: +34 96166 71 24 Correo electrónico: info@rubberex.es



The product mentioned can be in contact with dry, acid, wet, fatty and alcoholic foods. Gentle touch gloves can be in contact with all types of food following the European Commission Guide regulation Guidelines 2021 Ispra, JRC125894 testing conditions for articles in contact with food stuffs 30 minutes at a temperature of 40°.

The European Union Reference Laboratory for Food Contact Materials (EURL-FCM) and the National Reference Laboratories (NRLs) of the network have agreed on a set of test conditions, i.e. contact temperature and contact time, to ensure the comparability of measurement results reported in the frame of the implementation of official controls for FCM (Regulation (EU) 2017/625).

The test conditions for specific migration from plastics and plastic containing articles are based on expert judgement on the “worst case” foreseeable conditions of use by the consumer, followed by the application of the principles of sections 2.1.3 and 2.1.4 of Annex V of Regulation (EU) No 10/2011(#). Section 3.1 of the same Regulation applies to test conditions for overall migration.

Referencia / Reference: 2023TM0648-S01

Ensayos de migración global Overall <i>Migration Tests</i>	Norma <i>Standard</i>	Resultados ⁽¹⁾ <i>Results</i> (mg/dm ²)	Requisito ⁽²⁾ <i>Requirement</i> (mg/dm ²)
DETERMINACIÓN DE LA MIGRACIÓN GLOBAL EN ETANOL 50 % (D1) <i>DETERMINATION OF THE OVERALL MIGRATION IN ETHANOL 50 % (D1)</i>	EN 1186-3:2022	3,3 ± 0,3	10
DETERMINACIÓN DE LA MIGRACIÓN GLOBAL EN ÁCIDO ACÉTICO 3 % (B) <i>DETERMINATION OF THE OVERALL MIGRATION IN ACETIC ACID 3 % (B)</i>	EN 1186-3:2022	2,8 ± 0,3	10
DETERMINACIÓN DE LA MIGRACIÓN GLOBAL EN ACEITE DE OLIVA (D2)* <i>DETERMINATION OF THE OVERALL MIGRATION IN OLIVE OIL (D2)*</i>	EN 1186-2:2022	3,0	10

The raw material used for the manufacture of the glove complies with the conditions described in the legislation and are included in the positive lists of monomers and other starting substances and additives authorized for the manufacture of materials and articles intended to come into contact with food, without producing specific migration according to Values defined in the legislation.

The quality controls and tests have been prepared by the Aitex laboratory, located in Plaza Emilio Sala, 1 in Alcoy (Alicante) Spain. With test number Report 2023TM0648 issued on December 2023, for global migrations.

This declaration is valid for a period of 3 years from the present date and will be reviewed if there are any changes in the legislation, raw material or production process that may alter the conditions of conformity of the product.

En Valencia a 28/12/2023



Rubberex Spain S.L.U
Regulatory affairs

Erica Parra

Rubberex Spain S.L

VALENCIA, ESPAÑA, 46190

Teléfono: +34 96166 71 24 Correo electrónico: info@rubberex.es