

EU Declaration of conformity



This declaration of conformity is issued under the sole responsibility of the manufacturer Ejendals AB. The object described is in conformity with Union harmonization legislation Personal Protective Equipment (PPE) Regulation EU 2016/425.

TEGERA® 73

Medium risk



REFERENCES TO HARMONIZED STANDARDS TO WHICH CONFORMITY IS DECLARED

EN 388:2016, EN 420:2003 + A1:2009

The article meets relevant requirements in European Regulation 1935/2004 (Materials in contact with food) and European Regulation 2023/2006 (GMP). The regulation 10/2011/EC excludes rubber material, instead reference to Bfr (Bundesinstitut für Risikobewertung) which clarifies test conditions 10 min, 40°C for gloves.

IDENTIFICATION/NUMBER OF CERTIFICATION

0075/1203/162/05/20/1426

CERTIFICATION DATE

2020-05-11

CERTIFICATION EXPIRY DATE

2025-05-11

EU-TYPE EXAMINATION

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Leksand 2020-05-11

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FOOD CONTACT

Declaration of product compliance

This declaration of conformity is issued under the sole responsibility of the manufacturer Ejendals AB. The object described below belonging to the Textiles category, is in conformity with the following provisions:

TEGERA® 73

The EC-regulation 1935/2004 and the EC-regulation 2023/2006 related to Good Manufacturing Practices (GMP) for Materials and Articles intended to encounter Foodstuffs (for more detailed information please consult Ejendals AB). All ingredients, starting monomers, additives used in manufacturing this glove comply with relevant national food legislation(s):

Overall migration data

TYPE OF FOODSTUFF	AQUEOUS FOOD	ALCOHOLIC FOOD	ACIDIC FOOD	FATTY FOOD CORRECTION FACTOR 1	FATTY FOOD CORRECTION FACTOR 2	FATTY FOOD CORRECTION FACTOR 3	FATTY FOOD CORRECTION FACTOR 4	FATTY FOOD CORRECTION FACTOR 5
Testing conditions	Simulant: Distilled water	Simulant: Ethanol 10%	Simulant: Acetic acid 3%	Simulant: Olive oil	Simulant: Olive oil	Simulant: Olive oil	Simulant: Olive oil	Simulant: Olive oil
2h, 40°C	<8 mg/dm ²	<8 mg/dm ²	<8 mg/dm ²	<8 mg/dm ²	<8 mg/dm ²	<8 mg/dm ²	<8 mg/dm ²	<8 mg/dm ²
10 min, 40°C	<10 mg/dm ²	<10 mg/dm ²	<50 mg/dm ²	-	-	-	-	-

Analytical tolerance for aqueous, alcoholic, and acidic food simulant is 1 mg/dm² and for fatty food simulant 3 mg/dm² as per EN 1186

This compliance statement is based on information received from material suppliers. Supporting documents are available and can be disclosed to the competent authority on request.

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