



TEGERA® 71000

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 Elastomers & Rubber, Plastics categories, is in conformity with the following provisions:

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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):

COMMISSION REGULATION (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and all its amendments.

Germany: BfR Empfehlung XXI (2021) Bedarfsgegenstände auf Basis von Natur- und Synthetikgummi.

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	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²
10 min, 40°C	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	<10 mg/dm ²	-	-	-	-

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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.

Leksand 2023-05-25



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