FOOD DECLARATION OF PRODUCT COMPLIANCE

The Business Operator, established in the European Community:

ANSELL HEALTHCARE EUROPE N.V. RIVERSIDE BUSINESS PARK, BLOCK J BOULEVARD INTERNATIONAL 5 5B-1070 BRUSSELS

declares that the glove described hereafter:

AlphaTec™ 04-005

belonging to the "Plastic" category, is in conformity with the following provisions:

- Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food
- Regulation (EC) No 2023/2006 on Good Manufacturing Practices (GMP) for materials and articles intended to come into contact with foodstuffs
- Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, including all its amendments
- Regulation (EU) 2025/351, amending Regulation (EU) No 10/2011 and Regulation (EC) No 2023/2006

All ingredients, including starting monomers and additives used in the manufacturing of this glove, comply with any applicable positive list and any relevant SML (Specific Migration Limits) or restrictions as specified in the applicable EU food legislations.

Regulation (EU) 2024/3190 - no Bisphenol A (BPA) or other hazardous bisphenols are intentionally added to the product formulation of Ansell food contact approved products. Based on a review of the raw materials and formulation information, the product is considered to be in line with the requirements of Regulation (EU) 2024/3190, as corrected by Commission Regulation (EU) 2026/250, specifically:

- Article 3 – Prohibition of the use of BPA: Bisphenol A is not used as an ingredient in product formulation.
- Article 4 – Prohibition on the presence of BPA in food contact materials and articles for which other bisphenols or bisphenol derivatives are used: No BPA is present as a result of the use of other bisphenols or bisphenol derivatives in the formulation.
- Article 5 – Prohibition of the use of hazardous bisphenols: No hazardous bisphenols, as defined under Regulation (EU) 2024/3190, are intentionally used in the product formulation.

This statement is based on current formulation knowledge and supplier information and applies to the product as manufactured under normal, controlled production conditions.

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Global migration data:

Type of foodstuffs - Testing conditions	Aqueous food	Alcoholic food *Simulant used: Ethanol 10%*	Acidic food *Simulant used: Acetic acid 3%*	Fatty food correction factor 1 *Simulant used: Ethanol 95%/Isooctane*	Fatty food correction factor 2 *Simulant used: Ethanol 95%/Isooctane*	Fatty food correction factor 3 *Simulant used: Ethanol 95%/Isooctane*	Fatty food correction factor 4 *Simulant used: Ethanol 95%/Isooctane*	Fatty food correction factor 5 *Simulant used: Ethanol 95%/Isooctane*
2 hours/temp. 40°C	< 10 mg/dm²		< 10 mg/dm²					> 10 mg/dm²
10min/40°C								

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

Storage instruction: Keep away from direct sunlight; store in a cool dry place and keep in the original packaging. Keep away from ozone sources. If gloves are properly stored, as indicated above, they won't lose their performances and won't change the glove characteristics significantly. If gloves could be affected by ageing or storage, the expiry date is mentioned on the packaging materials.

Guido Van Duren
Director - Regulatory affairs
Ansell

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