Ansell Healthcare Europe N.V.
Riverside Business Park | Block J | Tel. 32 (0)2-528 74 00
Boulevard International 55 | B-1070 Brussels | Fax 32 (0)2-528 74 01

Good Manufacturing Practices Declaration for Ansell's materials and articles intended to come in contact with food

Herewith, the undersigned declares that all Ansell aprons that are intended for contact with Food products are manufactured in accordance with the following requirements:

Regulation 1935/2004:

- Aprons are sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.
- Aprons are made with only legally acceptable Food-contact ingredients and do not exceed any legal migration levels based on the intended use of the product.
Raw materials used in the production of the aprons are specified safe for food contact and are procured from an approved supplier.

Regulation 2023/2006:

- Aprons are made as per 'Good manufacturing practice (GMP)' meaning they are consistently produced and controlled to ensure conformity with the applicable rules and applicable quality standards. This applies to all activities, from procurement through approved suppliers of materials and all aspects of manufacturing, processing, handling, storage, transport and distribution of the finished article.
- The manufacturing plant has a documented and effective quality assurance system with the purpose of ensuring that materials and articles are of the quality required to ensure conformity with the rules applicable to them and the quality standards necessary for their intended use.
- The qualifications and training of personnel at manufacturing is documented. As well, the manufacturing facility and equipment is designed, cleaned, and maintained as necessary to ensure that in process materials and finished glove products comply with their specifications. Inherent in these requirements are personnel hygiene, pest control, contamination control, prevention of material damage from the environment, etc., etc.

- The manufacturing plant has an effective quality control system and a documented system of tests, inspections, document reviews and formal dispositions on raw materials, in process materials and finished articles. This system includes clear

decision-making criteria on materials and articles not meeting specifications.
- The manufacturing's quality control system monitors compliance with Good Manufacturing Practices and correct any failure to comply with GMP without delay. Ansell shall ensure adherence to the effective implementation of GMP through review of the supplier's internal audit system as described in the ISO 9001 Quality Management System.
- The manufacturing site maintains documentation on specifications, manufacturing formulae, and processing necessary to achieve regulatory compliance and product safety in electronic or paper (hard copy) format.
- Finished articles must be labelled with a unique control number, which relates to specific records held by the manufacturer.

Guido Van Duren
Director – Global Regulatory Affairs
PPE products
Ansell

Ansell Healthcare Europe N.V.
Riverside Business Park, Block J - Boulevard International 55 - B-1070 Brussels, Belgium
Tel. +32 (0) 2 528 74 00 - Fax +32 (0) 2 528 74 01 - Fax Customer Service +32 (0) 2 528 74 03
http://www.ansell.eu - E-mail info@ansell.eu

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