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

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

Regulation (EC) No 1935/2004:

- Gloves 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 deterioration in its organoleptic properties.
- Gloves 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 gloves are specified safe for food contact and are procured from an approved supplier.

Regulation (EC) No 2023/2006 and its amendment Commission Regulation (EU) 2025/351 (applicable to plastic category only):

- Gloves are made as per 'Good manufacturing practice (GMP)' meaning they are 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 in place 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.
- A formal risk analysis according to an established procedure has been conducted and each proposed change for its impact on risk to the user of the finished article is documented.
- 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 corrects 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 are 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

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