



Statement of Animal Origin

Catalog Number: **P2B010V05**

Item Description: PEL2 B 10K V 0.5M2

Millipore products do not contain materials of construction that are considered specified TSE or BSE risk materials (SRMs). Millipore's filtration and disposable product lines include many products which contain plastics that may come into contact with finished food, drug, or cosmetic products. Some products may be manufactured with polypropylene and or polycarbonate which may contain tallow derivatives, e.g. stearates as processing aids. These derivatives are produced by subjecting tallow to chemical processes (hydrolysis, trans-esterification, or saponification) that involve high temperature, time, pressure or distillation.

To the best of our knowledge and based on the information received from our suppliers in response to Millipore's Material Sourcing Questionnaire, some raw materials, direct packaging, or process materials contain animal derived materials as outlined below:

A raw material contains a tallow-derived material that originates from bovine sourced from the United States, Australia and Japan. The supplier has stated that the animal is fit for human consumption. The supplier has also stated the following processing conditions for the tallow-derived material: trans-esterification or hydrolysis at not less than 200°C for not less than 20 minutes under pressure, and distillation at 200°C. The processing conditions meet the requirements of the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products" (EMA/410/01).

A raw material contains a fatty acid and a tallow-derived material that originates from bovine sourced from the United States and Canada. The supplier has stated the following processing conditions for the fatty acid and tallow-derived material: trans-esterification or hydrolysis at not less than 200°C for not less than 20 minutes under pressure. The fatty acid is treated under a condition over 200°C for 60 minutes. The processing conditions meet the requirements of the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products" (EMA/410/01).

A raw material contains stearates that may originate from animals. The supplier has stated the following processing conditions for the fat-derived material: trans-esterification or hydrolysis at not less than 200°C for not less than 20 minutes under pressure. The supplier has stated that the material is processed in accordance with the requirements of the "Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products" (EMA/410/01).

Fungay Rowlette

Quality Assurance/Regulatory Affairs

Millipore's Quality Compliance includes a Material Sourcing and Animal Origin Program to actively manage its supply chain to ensure compliance with applicable regulatory requirements.

The wording or format of this statement has been modified for clarification only. Please contact Tech Service at 1-800-MILLIPORE with any questions.

Revision: B

Revision date: 16-Jun-2011

Mfg Location: JF