



Statement of Animal Origin

Catalog Number: P3C030C10

Item Description: Pellicon 3 Cassette Utracel PLCTK 30kD 1.14m2 cassette

Based on the information received from our suppliers, some raw materials contain animal derived materials. The information we have received from our suppliers is summarized 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 Rev. 2).

A raw material contains a tallow-derived material that originates from bovine sourced from the United States, Canada and Mexico. The supplier has 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 Rev. 2).

A raw material contains calcium stearate used as a trace stabilizer derived from animal fat that originates from animals sourced from the United States, Canada and Mexico. The supplier has stated the following processing conditions for the fat-derived material: multi-step chemical treatment involving high temperatures, high pressures, and long residence times. 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 Rev. 2).

A material that contacts the product during the manufacturing process contains stearic acid derived from tallow that originates from bovine. The supplier states the animals are healthy. The supplier has 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. 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 Rev. 2).

Furgay Rowlette

Quality Assurance

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: E

Revision date: 17-Jun-2009

Mfg Location: JF