



## Statement of Animal Origin

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Catalog Number: KHGE03TH3

Item Description: Gamma Opticap XL 3 Express SHC 0.5/0.2um TC/HB 3/pk

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 material that contacts the product during the manufacturing process contains small amounts of stearic acid derived from tallow that originates from bovine sourced from the United States and Mexico. The supplier has stated the following processing conditions for the tallow-derived material: processing times and conditions meet the requirements of the Commission of the European Communities (EC) Published Guidelines 2000/6/EC and 2001 OJ C 286 (October 12, 2001). 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" (EMEA/410/01 Rev. 2).

A raw material contains a tallow-derived material that originates from bovine sourced from the United States. 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 saponification with NaOH 12M: Batch Process at not less than 95°C for not less than 3 hours, 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" (EMEA/410/01 Rev. 2).

A raw material contains a tallow-derived material that originates from bovine sourced from the United States 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. 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" (EMEA/410/01 Rev. 2).

*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: C

Revision date: 22-Nov-2010

Mfg Location: JF