



## Statement of Animal Origin

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Catalog Number: KHGES05TH1

Item Description: Sterile Opticap XL 5 Express SHC 0.5/0.2 TC/HB 1/pk

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 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 and Canada. The supplier has stated the following process conditions for the tallow-derived material: processing at greater than 200 °C for a minimum of 20 minutes which meets the requirements of the World Health Organization, U.S. Food and Drug Administration and Commission Directive 92/562/EC. 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).

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).

*Fungay 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: A

Revision date: 03/19/2008

Mfg Location: JF