



Statement of Animal Origin

Catalog Number: PXC005C50

Item Description: PELXL PL5K 50CM2

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 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" (EMEA/410/01 Rev. 2).

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" (EMEA/410/01 Rev. 2).

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" (EMEA/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" (EMEA/410/01 Rev. 2).

A raw material contains an additive that is derived from bovine material sourced from the United States, Canada and Mexico. The supplier has stated the following processing conditions for the bovine material: trans-esterification or hydrolysis at not less than 200°C for not less than 20 minutes under pressure, and distillation at 200°C; hydrogenation of stearic acid at 232°C and 300 psig for 2.5 hours, and distillation at 232°C for 5 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" (EMEA/410/01 Rev. 2).

Fungayi 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: C

Revision date: 10-Jun-2009

Mfg Location: JF