



Statement of Animal Origin

Catalog Number: P2B050V01

Item Description: PEL 2 B 50K V 0.1M2

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. 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. 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 and porcine sourced from the United States and Canada. 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. 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 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. 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 and porcine sourced from the United States, Canada, 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. 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 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. 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).

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.

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Mfg Location: JF