Quality Certificate

VWR* POLYSTYRENE INOCULATING LOOP

This document certifies that this product meets the following criteria:

Product Number :	12000-808
Lot Number :	103162
Description :	VWR LOOP INOCULATIN 1UL CS1000
Minimum Specified Dose :	6.0 KGy
Maximum Specified Dose :	12.5 Kgy
Sterility Expiration Date :	05/2016

Remarks:

Each shipment of the above product that goes to the sterilisation is verified by inserting a sample in a few cases of product to be shipped. These samples are then sent to an independent laboratory to verify their sterility. All product that is then shipped to has passed this sterilisation test. The Specific Dose of irradiation for this is a minimum of 6.0 and a maximum of 12.5 Kgy, for an average dose of 9.25 Kgy.

BSE/TSE Statement:

The below product is made from HIPS of which the resin supplier has confirmed the following information:

Some additives used in this product grade are manufactured from raw materials including bovine derived tallow. The tallow additive is used at a low loading level. The additive supplier certifies that the tallow, primarily bovine, is what is known as inedible tallow and is sourced entirely from the USA , Mexico and Canada. Further the production process (post tallow) may include hydrolysis at 260_oC, 700 psig for more than two hours; hydrogenation above 200_oC, 300 psig for more than two hours; distillation; and reaction with base (high pH) at 90^oC for 30 minutes. That is, the manufacturing conditions in the production of the tallow derivatives are not only consistent with, but exceed those considered as “rigorous processes” by the European Committee for Proprietary and Medicinal Products (CPMP), EMEA 410/01, Committee for Vetrinary Medicinal Products (CVMP) as revised 2004/C 24/03, Section 6.4E and EU Council decision 99/534/EC.

As stated in EMEA 410/01 note for guidance , tallow derivatives manufactured under conditions atleast this rigorous are considered to be in compliance and are unlikely to present any TSE risk.

Pursuant to the production of tallow derived chemicals, U.S manufacturers may undergo inspections and audits, bth internal and external, in compliance with Good Manufacturing Practices, and ISO 9000 quality managament practices. These factors:1)Control of tallow feed stocks, 2)The manufacturing operations that include harsh temperatures (above 200oC) and pressures, as well as high pH (greater than 12) , 3)Surveillance of animal health, 4)Auditing practices to assure adherence to regulatory and quality procedures further support the conclusion of negligible risk from transmission of this disease.

Signed:

Ken Crossley
Manager
Quality Assurance

Date of Issue: June 7, 2011