BSE/TSE STATEMENT

VWR* FLASK

This document certifies that this product meets the following criteria:

North American Catalog No:	89095-282
Description:	VWR FLASK PC 1L STERILE CS25

The **polycarbonate** resin used to manufacture the above product complies with the requirements of the U.S. FDA's **21 CFR 177.1580** for food and drug contact applications. Though a component in the resin is made with tallow, the resin in this product meets the requirements of *(*EMEA/410/01 Current Revision) Note for Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products by virtue of being processed in accordance with section 6.4 requirements.

The **polypropylene** resin used to produce the caps on the above product contains one additive that is derived from animal sources. Their suppliers have stated that the additive is from bovine material. They have assured the resin manufacturer that the animal material is sourced from the United States, Canada or Mexico. The bovine material can be any part of the animal. There are 2 sets of process conditions specified by the suppliers for the bovine material. These are as follow:

- Hydrogenation of tallow @ 200° C, hydrolysis @ 260° C, and 48 bar for 1.5 – 2 hours and vacuum distillation @ 232° C.

- Hydrolysis of tallow @ 260° C and 700 psig for 3 hours, hydrogenation of stearic acid @232° C and 300 psig for 2.5 hours, and distilled at 232° C for 5 minutes.

The **Orange colorant** which is used to produce the caps for the above product contains zinc
stearate and ethylene bisstearamide (EBS).

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Zinc Stearate:

The tallow feedstocks used to produce the zinc stearate are sourced exclusively from within the United States. The United States Department of Agriculture (USDA) has had a BSE surveillance system since 1986. In 1989, the USDA banned imports of live bovine and ovine animals and animal products form the UK and later extended the ban to all BSE infected countries as listed in 9CFR Part 94. In 1997, the FDA banned the use of mammalian protein in cattle feed providing another significant barrier. In addition, the US Federal government has taken other steps to protect human and animal health against BSE. In combination, these measures provide assurance that the domestic tallow supply is contained in those areas where the proper safeguards to BSE transmission are in place. A description of the manufacturing process used includes the following information. Fatty acids are formed form the tallow using harsh temperatures, pressures, and prolonged residence times. The hydrolysis step is carried out at sustained temperatures of over 400F and ape pressures exceeding 600 psi pressure and a residence time of approximately 3 hours. The fatty acids also undergo further purification, including distillation at temperatures greater than 400F. The distillation process produces fatty acids free of unwanted impurities.

Ethylene Bisstearamide (EBS)

Ethylene bisstearamide (EBS) is derived form stearoyl compounds. It is manufactured partly from animal sources of continental European origin, U>S> and Canada. The animal fat is broken down into glycerol and fatty acids (palmitic and stearic acid) by hydrolysis at high temperatures (>200° C), for several hours under high pressure and is purified to comply with the European directive 98/16/EC. The additive is further processed into amides by chemical conversion. Based upon the above information, this material is considered BSE/TSE free on account of the manufacturing process, despite the presence of additives of animal origin.

The **membrane material** which is used in all the vent caps does not contain any materials of animal origin.

Signed:



Ken Crossley
Manager
Quality Assurance

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