

## **BSE/TSE STATEMENT**

## **VWR\* SOFTGUARD\* BARRIER HAND CREAM**

This document certifies that the below product meets the following criteria:

North American Catalog No:	56614-414
Description:	VWR SOFTGUARD HANDCREAM 16OZ

The above product is derived from lanolin which comes from sheep's wool grease, and originates from Australia, New Zeland, China, Argentina, Uruguay, South africa, USA, Spain, Italy, Germany, and Czech Republic.

According to EMEA/410/01 Rev.2, this product conforms to the folloeing guidelines:

- (i) The wool grease is sourced from live sheep and therefore already exempt from certification requirements.
- (ii) The product is subjected to conditions in excess of the required treatment at pH>=13(initial;corresponding to a concentration of at least 0.1M NaOH) at >=60C for at least 1 hour during manufacture.

It does not contain any bovine or caprine material, and does not contain any ovine material other than lanolin. Additionally, wool/hair and its derivatives, such as wool alcohols and lanolin, are recognized as being unlikely to be contaminated [Ref 1,2,3]

## References:

[1] Commission of the European Communities, (May 1992), The rules governing medicinal products in the European Community-Volume III, Addendum 2, p117-125.

[2]Fedearl Health Office (BGA), (1992), Guidelines on safety measures in connection with medicinal products containing body materials obtained from cattle, sheep or goats for minimizing the risk of transmission of BSE and scrapie, Bundesanzeiger No.40, 26/2/1994.

[3]World Health Organization, (1992), Public health issues related to animal and human spongiform encephalopathies: memorandum from a WHO meeting. Bulletin of the World Health Organization, 70 (2) p183-190.

Signed:

Ken Crossley Manager

Quality Assurance

Date: September 19,2012